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Agency for Toxic Substances and Disease Registry

Division of Health Studies

FINAL REPORT

Madison County Lead Exposure Study

Illinois Department of Public Health Springfield, Illinois

April 1995

U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Agency for Toxic Substances
and Disease Registry
Atlanta, Georgia 30333

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
AGENCY FOR TOXIC SUBSTANCES AND DISEASE REGISTRY
ATLANTA, GEORGIA

MADISON COUNTY LEAD EXPOSURE STUDY GRANITE CITY, ILLINOIS

ILLINOIS DEPARTMENT OF PUBLIC HEALTH
SPRINGFIELD, ILLINOIS

April 1995

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CONTENTS

LIST OF TABLES

LIST OF FIGURES

LIST OF APPENDICES

ABSTRACT

A lead exposure study of 827 participants was conducted around a closed secondary lead smelter in August and September of 1991 in Granite City, Illinois. The arithmetic mean venous blood lead level in 490 children under 6 years of age was 0.33 μmol/L (6.9 μg/dl), with a range of 0.03 to 1.94 μmol/L (0.7 to 40.2 μg/dl). The blood lead levels were log-normally distributed with a geometric mean of 0.27 μmol/L (5.58 μg/dl). Of the 78 children under 6 years of age with blood lead levels ≥0.48 μmol/L (≥10 μg/dl) only 5 children had a blood lead level >1.21 μmol/L (>25 μg/dl). Blood lead levels in 214 youths from 6 through 15 years of age were lower, with a mean of 0.33 μmol/L (4.4 μg/dl) and a range of <0.03 to 0.90 μmol/L (<0.6 to 18.8 μg/dl). Only 8 children in this group had blood lead levels ≥0.48 μmol/L (≥10 μg/dl). Mean blood lead levels in adults were 0.17 μmol/L (3.6 μg/dl) and in 14 pregnant women 0.08 μmol/L (1.6 μg/dl). Complete blood counts and a battery of clinical laboratory tests revealed occasional abnormal findings unrelated to lead exposure.

Many houses in this community were built before 1920 and some were in poor condition. Seventy percent (70%) of interior paint and eighty percent (80%) of outside paint in those houses contained > 1 mg/cm^2 of lead, and many lead paint measurements were >6 mg/cm^2. The levels of lead in composite soil from the yards of these houses ranged from 37 to 3,010 mg/kg (37 to 3,010 ppm) and the concentration of lead in house dust ranged from 5.2 to 71,000 mg/kg (5.2 to 71,000 ppm) on a weight basis and from 0.02 to 58,800 μg/m^2 on a surface area basis.

Blood lead levels in children tended to be higher as the condition of the house they lived in and their parents' education and income level decreased. Houses with higher lead paint levels had higher soil lead levels but the soil had little effect on blood lead levels.

The mean blood lead level of children living in houses in good condition was 0.29 μmol/L (6 μg/dl). Children living in houses in fair condition had mean blood lead levels of 0.4 μmol/L (8.2 μg/dl) and children living in houses in poor condition had mean blood lead levels of 0.57 μmol/L (11.8 μg/dl). The dust load was higher in houses in poor condition than in houses in good condition.

Regression analysis showed that lead in paint alone accounted for 3% of the variance in children's blood lead levels. Lead in paint and the condition of the houses together accounted for 11% of the variance in blood lead. Adding soil lead to the regression equation for lead in paint and the condition of the houses accounted for an additional 3% of the variance in blood lead. Only 40% of the variance in blood lead could be accounted for by including all of the variables in the study.

MADISON COUNTY
LEAD EXPOSURE STUDY
GRANITE CITY, ILLINOIS

INTRODUCTION

The NL Industries/Taracorp site is located in a mixed industrial and residential area in the City of Granite City, Illinois. Taracorp is one of 41 National Priority List (NPL or Superfund) hazardous waste sites in Illinois. The Illinois Department of Public Health (IDPH), in conjunction with the Agency for Toxic Substances and Disease Registry (ATSDR), evaluates each Illinois Superfund site's potential to harm public health.

The study described in this report was undertaken as part of a larger study of lead contamination at Superfund sites in several states. The objectives of the Illinois part of this study were:

1. To determine the concentration of lead and cadmium in blood and urine in target populations.

2. To determine the level of lead and cadmium contamination in environmental media in target areas.

3. To compare these levels with levels of contamination observed in a comparable nontarget area which in this part of the study was a continuum of the target area.

4. To determine how distance from the point source was related to blood lead levels, levels of lead in soil and in paint and to the condition of the houses and other elicited variables.

5. To evaluate the contributions of various environmental sources of lead (paint, soil, drinking water and house dust) to the overall lead exposure of children.

6. To examine the impact of a number of variables (such as socioeconomic factors, behavioral factors of the children and awareness of parents of the pathways of lead exposure) on lead exposure and lead uptake by children.

In addition to the Illinois study, the multistate study included three mining and/or smelting sites where the potential for exposure to lead and cadmium existed. The objectives in these studies were similar. Cadmium was not present in higher than background concentrations in the Granite City, Illinois area, however, for the sake of consistency, cadmium data were collected.

BACKGROUND

The population within a 3-mile radius of the Taracorp site numbers 34,000 and the closest residents live within 100 yards of the boundary of the site. Although the site is located in Granite City, two other towns, Madison and Venice, are also located in close proximity to the site. A map is attached to illustrate the area (Figure 1).

Industrial History

Operations at the site started in 1895 as the Markle Lead Works. The Markle Lead Works manufactured lead shot and clay pigeons. Fire destroyed most of the facility in November 1900. In 1901, the plant was rebuilt and included a lead smelter. Prior to 1903, processes at the site included manufacturing lead shot, sealing wax, mixed metal, rolled sheet metal, and dross refining. Between 1895 and 1903, Hoyt Metals purchased the site from the Markle Lead Works. In 1903, United Lead purchased the smelter from Hoyt Metals and added secondary smelting capabilities. In 1928, NL Industries (formerly National Lead Company) acquired the smelter from United Lead. Battery recycling began in the 1950s. In 1979, NL Industries sold the site to its present owner, Taracorp Industries.

Taracorp operated a secondary smelter with the capacity to produce 22,000 tons of lead products per year. In 1983, Taracorp ceased smelting in an effort to reduce lead air emissions but continued to operate the metal refining and fabricating facilities at the site. A slag storage area is located on the southern boundary of the site. A preliminary site assessment performed in May 1983, estimated that 200,000 tons of lead waste were present at the site. Most of this waste was in and around the slag storage area. The slag storage area contains slag, metallic lead, lead oxide, cadmium, arsenic, iron oxide, silica, rubber and plastic battery cases, general refuse, drums, and matte.

St. Louis Lead Recyclers (SLLR) borders Taracorp on its southwest boundary. SLLR was originally established in 1980 to reclaim lead from batteries. In 1982, SLLR reached an agreement with Taracorp, allowing SLLR to recycle various materials from Taracorp. From 1981 to 1983, SLLR processed an estimated 11,000 tons of material from Taracorp's slag pile. Materials that could not be recycled (for example, slag and hard rubber) were placed southwest of the slag pile. In June 1983, SLLR discontinued recycling lead from the slag pile.

Trust 454, Terminal Railroad Associates Inc., Illinois Central Gulf Railroad, Chicago and Northwestern Railroad, and Tri-Cities Trucking Inc. own properties bordering the site. SLLR is the present tenant on the land owned by Trust 454.

Dross is the name given waste products or impurities from the surface of molten metal.

Secondary smelting is the process of smelting lead-bearing materials other than ores such as slag or matte (a by-product of smelting containing metal sulfides and metal oxides).

The now closed secondary lead smelter contributed to off-site soil contamination during 80 years of airborne lead emissions related to smelting, surface runoff, and fugitive dust emissions from contaminated on-site surface soil and slag piles. The site achieved NPL status in 1984 and ceased smelting operations in 1983.

Characterization of the Site Prior to the Study

Soil

Soil samples collected from the industrial site in 1988 contained lead in concentrations ranging from 1,500 to 48,000 mg/kg (1,500 to 48,000 ppm). Slag piles and other surface wastes were estimated to contain up to 300,000 mg/kg (300,000 ppm) of lead. On-site cadmium soil concentrations in 37 samples ranged from <2 to 12 mg/kg (<2 to 12 ppm). Off-site samples collected from residential yards and gardens revealed lead concentrations that ranged from 106 to 9,493 mg/kg (106 to 9,493 ppm) (mean = 1,030 ppm, median = 905 ppm, n = 40 ppm) and cadmium concentrations of 0.4 to 15.7 mg/kg (0.4 to 15.7 ppm).

Surface Water

The two main surface bodies of water, the Mississippi River and Horseshoe Lake are located at least two miles from the site. The Mississippi River is monitored regularly for compliance with quality standards and drinking water standards and has thus far not shown any discernable site-related heavy metal contamination. Although monitored less frequently, Horseshoe Lake has no history of potentially site-related contamination. The distance from the site and the potential environmental mobility of site-related contaminants make such contamination unlikely.

Air

Ambient air monitoring has been performed since the late 1970s by the Illinois Environmental Protection Agency (IEPA). Air lead levels taken from monitors closest to the site regularly exceeded the 1.5 $\mu g/m^3$ National Ambient Air Quality Standard (NAAQS) for lead during the 1970s and early 1980s. The highest quarterly average recorded during the final months of 1981 was 7.3 $\mu g/m^3$, while the 1981 yearly average was 3.03 $\mu g/m^3$. Because of persistent air standard violations, Taracorp was denied a state license to operate the smelter in 1983. Since the smelter ceased operations, air lead levels have remained below the NAAQS standard.

Groundwater and Dust Samples

Groundwater contamination by inorganics directly under the site has occurred. However, this water is not used for drinking purposes and the contamination does not appear to have moved any distance off-site. No information was available on concentrations of lead or cadmium in house dust prior to this study.

Human Exposure

In 1982 and 1983, IDPH determined blood lead levels in a total of 99 individuals from 43 households within 3.2 km of the secondary lead smelter in Granite City and Madison. This group included 47 children under 6 years of age. The mean blood lead level of these children at that time was 0.64 μmol/L (13.2 μg/dl) with a range of 0.05 to 1.79 μmol/L (1 to 37 μg/dl). In 1983, similar blood lead levels were found in 31 children in Venice, an adjacent town to Granite City. At that time, the mean blood lead level in the United States for children under 6 years of age was 0.73 μmol/L (15 μg/dl).

The IDPH, together with ATSDR, completed a health assessment of the Taracorp NPL site in 1991. Based on the extent of lead contamination and possible human exposure, a potential health risk was deemed to exist. That finding, along with citizen concerns, prompted this exposure study.

METHODS

Rationale for Study Design

In the absence of a totally geographically separate comparison area, the primary hypothesis to be tested for this cross-sectional study using regression analysis was whether lead in soil contributed significantly to blood lead levels in children. It was postulated that, if soil lead was an important source of lead exposure, participants living farther away from the smelter would be less likely to have elevated blood lead levels than those living nearer.

Although other age groups were included in the study, the major focus was on children aged 6 through 71 months who had lived for at least three months at their present address. Blood lead levels are largely reflective of recent exposure and a three month residency was used to ensure that blood lead levels were associated with the current residence. Since young children are more susceptible to the effects of lead, and are more likely to be exposed, the sampling strategy for selecting study participants required the intentional over-sampling of this group. Smaller numbers of other eligible residents, aged 6 through 45 years and some older persons were included from the target and comparison areas.

Selection of the Target and Comparison Areas

In 1991, the NPL site or proposed cleanup area extended 0.8 km from the smelter. Following a site visit and a census by IDPH and Institute for Evaluating Health Risks (IEHR) in May of 1991, participants were recruited from within and from outside this area in concentric rings extending for another 3.2 km. No suitable comparison group that was not a continuum of the declaration area (the area proposed as the cleanup area by United States Environmental Protection Agency [USEPA]) could be identified. An attempt was made to include another residential area, Pontoon Beach; however, the houses there were built sometime during the last three decades or represented trailer parks of recent vintage. Within a reasonable distance from

the study site, no other small-to-medium sized towns could be identified with a housing stock of similar age and a population of similar socioeconomic status as the study area. It was, therefore, decided to recruit study participants from regions of Granite City, Madison, and Venice with similar housing stock but differing in proximity to the closed lead smelter. Since no separate control group was available, hypothesis testing comparisons in the Illinois part of the study primarily consisted of regression analyses. However, dichotomous analyses of the data were also performed by dividing the population into two groups using soil lead concentrations < 500 mg/kg (< 500 ppm) and ≥ 500 mg/kg (≥ 500 ppm) as cutoff points. This comparison reduced the sensitivity of the study, and might have introduced a bias since other relevant risk factors in the study population varied with soil lead concentration and distance from the closed smelter. Regression analyses were, therefore, the more appropriate approach.

Phase I: Census Survey and Enrollment of Participants

In the summer of 1991, a census of part of Granite City and all of the two adjacent towns of Venice and Madison was conducted by IDPH. Four residential sampling regions were defined based on IEPA data that suggested that the soil lead concentrations decreased with distance from the smelter. It was presumed that sampling region one, closest to the smelter, had the highest soil lead concentrations. This was the area placed on the NPL by the USEPA. Sampling region two was presumed to have soil lead concentrations ranging from slightly above to slightly below 500 mg/kg (500 ppm), while the soil lead concentrations in sampling regions three and four were presumed to be lower.

The initial definition of sampling regions was somewhat arbitrary without knowledge of exact soil lead concentrations in the four sampling regions. The objective was to achieve a fairly representative range of soil lead values. Exact soil lead data collected during the study replaced the initial sampling area designations.

A copy of the census form is attached (Appendix A). IDPH trained the interviewers and conducted the census. The census takers interviewed the head of household or a knowledgeable adult surrogate at each house. The census data were grouped into four sampling regions. Sampling region one occupied the smallest geographic area. Some houses in the second sampling region were still in the USEPA cleanup area while the houses in sampling region three and four were outside the cleanup area. Age, sex, and length of residence were recorded for each individual in each household. A 90-day residency was required to participate in the second phase of the study. This requirement insured that the children had spent the summer at their present residence and had time to develop blood lead levels indicative of their environment. The second phase consisted of collecting household and personal interview data, blood and urine specimens, and environmental samples.

Phase II: Interviews

All families in the census area with children under six years of age were contacted during the latter part of August and through September 1991 and invited to participate in the study.

The household identification number for each household that participated in the census was retained and used for the household questionnaire and the environmental samples. In addition, each participant received an identification number which was linked to the household identification number. All females listed as pregnant on the census forms were invited to participate in the study unless they had given birth in the interim. A number of families participated who did not have children under six years of age because the age of their children was entered erroneously on the census form or the children were six years old or older by the time the study was done. Overall, 33 families without a child under 6 years of age participated. One of these families was chosen because of pregnancy.

Appointments were made for interviews and specimen collection; participants were asked to come to a centrally located office to be interviewed and to visit St. Elizabeth Medical Center to donate blood and urine specimens. A consent form (Appendix B) approved by a human studies review board was explained to the participants, and each participant was asked to sign. A parent or guardian was asked to sign for each minor child. Minors capable of signing were also asked to do so. Participants were informed that all identifying information would be kept confidential and that personal identifiers would be removed prior to release of the data for publication or use by any government agency. Permission to obtain environmental samples at a later date was also obtained at the time of the interview.

The interview questionnaire (Appendix C) was administered by trained interviewers. Questions were asked about the household, occupation, hobbies, income, and education of the parents; behavior of the children; and all potential exposures to lead. The questionnaire consisted of two parts, one dealing with the household and one with the participant. Some questions in the household questionnaire dealing with mining activities and hobbies had fewer than 10 affirmative responses. The mining questions were irrelevant for the study in Illinois since this population did not engage in this occupation. They were included since the same questionnaire was also used for studies at the mining sites. These infrequent affirmative responses were not included in the statistical analyses. The questions concerning time spent in different locations were transformed to create a single variable expressing the average time spent at home. The participant questionnaires were separated by age: 6 through 71 months, 6 through 14 years, and 15 years and older.

Phase III: Biological Specimens

Following the interview, the participants donated venous blood and urine specimens at St. Elizabeth Medical Center. Blood specimens were obtained by trained pediatric phlebotomists. Urine was collected in either 250 ml sterile collection cups or 150 ml sterile collection bags for children not yet toilet trained. Details of the collection and handling of specimens, and laboratory methods are reported by Midwest Research Institute (MRI), Kansas City, Kansas (Appendix D).

Laboratory Methods and Quality Control

Clinical laboratory tests of blood and urine specimens are listed in Table 1. These tests were performed by either the Centers for Disease Control and Prevention (CDC) in Atlanta, Georgia, St Elizabeth Medical Center in Granite City, Illinois or the LaRoche Laboratories, Kansas City, Kansas (Appendix D). The transport and handling of specimens was supervised by MRI and CDC. The blood was analyzed for lead at CDC using a published method[1]. This method has a limit of detection of 0.03 μmol/L (0.6 μg/dl). Additional venous blood specimens were collected four months and one year later from children with an initial blood lead level greater than or equal to 0.48 μmol/L (10 μg/dl) and analyzed for lead at CDC. Urine samples were analyzed for cadmium according to the method reported by Pruszkowska et al.[2] with a limit of detection of 0.1 μg/L. Duplicate samples and quality control samples were also analyzed. This is described in detail by MRI in Appendix D.

Environmental Samples

Soil, house dust, and drinking water were collected by a contractor for USEPA-Region V (Chicago). In situ indoor paint analyses were performed by an experienced lead paint inspector on contract to USEPA using an X-ray fluorescence (XRF) device. A copy of the USEPA sampling protocol is appended (Appendix E). Up to 18 readings were taken in 3 frequently occupied rooms from walls and woodwork. The XK-3 XRF instruments used in this study lose their sensitivity at lead paint concentrations >10 mg/cm^2. The amount of lead in paint >10 mg/cm^2 was estimated using the average weekly calibration time to get a 10 mg/cm^2 reading and dividing the test reading by the ratio of the time to obtain a reading over the average calibration time. The condition of the paint where a reading was made on the inside of the house were rated as (1) intact, (2) slightly peeling, (3) moderately peeling, and (4) extremely deteriorated. The measurement of lead in outdoor paint was contracted through IDPH and the IEHR with the same contractor used by USEPA-Region V, (Chicago). Up to 12 exterior readings per house were made. For the outside of the house, three conditions were used: good, fair, and poor. Ratings for the exterior condition of the house were missing for 59 houses or 15%. A mean building condition score of 1.389 was assigned to those houses so that building condition could be used in the regression analyses. Building condition missing values were not associated with any other variable and regression analyses including a missing value dummy variable showed that this procedure had no effect on the calculations.

Soil samples were analyzed by EPA method 6010[3] using inductively coupled argon plasma (ICAP) emission spectroscopy. Both wet and dry soil lead levels and total solids were determined. Only the dry weight lead levels are reported here. Obvious paint chips were removed prior to soil analysis. A detailed description of the methods used to collect and analyze the environmental samples is appended (Appendices E, F, G, and H). Thirty-nine duplicate samples were analyzed as a quality control measure.

Lead in dust was analyzed using a technique similar to that used to analyze soil (Appendix H). The concentration of lead in house dust was not the best indicator of potential

lead exposure because the size of the different areas that had to be vacuumed to obtain sufficient dust varied. A variable, "dust load", was calculated by dividing the dust sample weight by the surface area vacuumed and multiplying that ratio by the dust lead concentration. The concentration of lead in drinking water was determined in a first draw sample from the kitchen tap of each household by graphite furnace atomic absorption spectrophotometry.

Cadmium was determined in house dust and soil by ICAP emission spectroscopy and in water by graphite furnace atomic absorption spectrophotometry.

The limit of detection for lead in house dust was 20 mg/kg (20 ppm), for soil $\leq$20 mg/kg ($\leq$20 ppm), and for drinking water $\leq$2.0 μg/L ($\leq$2.0 ppb). The limit of detection for cadmium in house dust was 2.0 mg/kg (2.0 ppm), for soil 1.0 mg/kg (1.0 ppm), and for drinking water $\leq$0.5 μg/L ($\leq$0.5 ppb).

Reporting of Results to Participants

The participants were informed of their individual clinical and environmental results by letter. The results of the clinical tests were presented at a public meeting in the spring of 1992 without revealing the identity of the participants to reassure residents and encourage parents or guardians of untested children to have them tested. All families with at least one child with a blood lead level of 0.48 μmol/L (10 μg/dl) or above were visited, and potential sources of lead in the immediate environment of the child were identified. The parents or guardians were instructed in nutrition, in personal hygiene of the children, and in reducing exposure through housekeeping and minor remediation of trouble spots in or outside of the residences.

DATA ANALYSIS METHODS

Data Entry and Transformation

Information from the census forms was entered into ASCII files and was manipulated by two microcomputer database management programs (dBase IV and BMDP-EM Data Manager). The precoded questionnaire data were directly entered into electronic data files. Key data were entered twice to assure accuracy. All laboratory data were supplied electronically and in hard copy by the different laboratories and contractors. For values below the limit of detection, half of the value of the limit of detection was used. For the XRF readings, the value 0.001 mg/cm^2 was used for zero readings to ensure that no cases were dropped during the calculations, since the log of 0 is treated as missing in the statistical program used for data analysis. This value of 0.001 mg/cm^2 did not affect the analysis.

The XRF data for five houses, lead levels in dust for six samples, lead levels in drinking water for four samples and the rating for 15% of the outside condition of the houses were missing. The missing data appeared to be random and no significant association was found between missing building condition and any other variable.

Since intact paint is less likely to result in exposure, the XRF reading was transformed by multiplying each paint XRF reading by its surface condition. The sum of all indoor paint conditions multiplied by the XRF readings for a house was divided by the number of measures taken to yield an average condition times XRF for each house. The same transformation was performed for the outdoor XRF readings. The transformed XRF variables produced modest improvements in correlations with blood lead.

The approximate distance and the direction of each house from the closed smelter was estimated by locating the houses on a map and measuring the distance with a ruler.

Statistical Analyses

The Statistical Analysis System (SAS)[4] for the microcomputer was used. Univariate (descriptive) statistics were run on all variables. Only summary statistics (means, medians, and ranges) are reported here. Distributions of the biologic and environmental data were positively skewed. Log transformation of these data resulted in more normal distribution. Where log-transformations were performed the geometric means of these variables were also reported.

Variable Selection

Simple bivariate Pearson correlations, analysis of variance, t-tests, and chi-square analyses (with high/low blood lead grouping of subjects under 6 years of age) were inspected to eliminate variables that did not appear to be associated with blood lead. However, some variables (for example, water lead) that could have been eliminated at this stage were retained based upon *a priori* hypotheses that all of the environmental samples would contain some lead and would have some impact on blood lead levels.

Bivariate analyses are presented for many combinations of variables. Blood lead values ≥ 0.48 μmol/L (≥ 10 μg/dl) were used to define the high blood lead group among children under 6 years of age for group comparisons and the more important predictor variables. The group living in regions with composite soil lead levels <500 mg/kg (<500 ppm) were compared to the group living in regions where the soil lead levels were ≥ 500 mg/kg (≥ 500 ppm).

Multiple regression/correlation modelling[5], which produces a set of multiple correlation coefficients, was conducted for three purposes. First, multiple regression was used to help identify variables that had some utility in predicting blood lead levels in this population. Second, a maximum regression coefficient R^2 improvement analysis was conducted to identify the set of variables with the greatest predictive utility. Finally, hierarchical regression modelling was conducted to evaluate the contribution of soil lead to blood lead and house dust lead. Hierarchial regression modelling involves the sequential addition of variables to a multiple regression equation. At each step in the sequence, a set of one or more variables is added to those already entered and a standard regression equation is derived. The incremental change in R^2 represents the independent contribution of the last set of variables to the total variance

accounted for by the regression model at that point. Hierarchical regression provides a means of testing the significance of a relationship while controlling statistically for the effects of other variables that could confound or modify the relationship.

Controlling for variables such as age, sex, and SES (socioeconomic status) can "overadjust" the relationship with blood lead and other key variables in the regression analysis. Therefore, only a very small set of predictor variables was analyzed through hierarchical regression.

RESULTS

Participation Rates

Census

The census resulted in the collection of 5,734 household census forms. Census workers were unable to interview anyone at 600 addresses (10.5%). Some of these addresses were believed to be vacant houses and apartments, but no definite occupancy determination could be made. There were 5,134 usable census forms. A total of 906 (17.6%) households met the initial qualification criterion for participation in the study. One or more children under 6 years of age had lived in these dwellings for at least 3 months. After screening visits or telephone calls, 116 households were disqualified because the family had moved since the census, they were away on vacation; all of the children were younger than 6 months or older than 6 years; the family had lived at the address for less than 3 months or the child in the family under 6 years of age no longer lived there, or had not yet lived there for 3 months.

Residents of the neighboring community of Pontoon Beach were included in the initial census; they were considered as a possible second group of study control subjects adjacent to the eastern border of Granite City and about 7.2 km removed from the closed smelter. However, Pontoon Beach residents were dropped from the final study target population because there appeared to be only 26 Pontoon Beach families in the census who qualified for selection and because the houses were newer or the children resided in a trailer park. This process of elimination resulted in a final "nominal" target population of 790 households. This number included households where, subsequent to administering the census questionnaire, no further contact was made.

Exposure Interviews

Of the 790 target households, 355 (45%) participated in the study. Another 33 participating families (not counted in the 45% participation rate) lived in the target regions, but none had a child under 6 years of age. The data for this group of 33 households were not used in the main analyses of this report.

A total of 266 (34%) households refused to participate. Most of the families that refused stated that they did not want to subject their child to the study's blood sampling procedure. Some of the adults contacted expressed hostility or distrust, in some cases confusing our study activities with the USEPA proposed cleanup of the site listed on the NPL.

Another 169 (21%) target households listed in the census could not be contacted, or were scheduled for, but missed, numerous appointments. Many of those who missed appointments did so for seemingly valid reasons (sickness, vacation, or work schedule conflicts), while some were rescheduled so many times that they were considered to be refusals. Most of households in this group population were difficult to contact. Of the 790 target households with young children, 30% had no telephone number on the census form, making follow-up contacts difficult even though the residences were visited several times. Study qualification, participation, and refusal rates are presented in Table 2.

Participation by Sampling Regions

The target population for this study was geographically divided into four sampling regions. The regions can be described as four approximate concentric circles, around the Taracorp site. The sampling regions were of unequal size, with sampling region one (closest to Taracorp) containing the smallest number of houses. This region, when the study was done in 1991, represented the potential cleanup area. It extended roughly 0.8 to 1.0 km in all directions from the Taracorp boundary. Sampling regions two and three were each roughly 0.8 to 1.0 km in width, and sampling region four was roughly 1.2 km in width. Participation by sampling regions is presented in Table 3. Participation rates were similar for each sampling region, with a slightly lower rate of participation in region four, the region farthest from Taracorp.

The participants lived in 388 separate households. Occasionally more than 1 family shared a household. There were 230 families with 1 child under the age of 6 years, 106 families with 2 children under the age of 6 years, and 14 families with 3 or more children under the age of 6 years. In some of the larger families, not all children had the same parents. A total of 212 youths aged 6 through 14 from 107 households were included in the study. Of these, 56 households had 1 youth and 51 had 2 or more, resulting in an average of 1.98 youths aged 6 through 14 years per household. A total of 123 youths, more than 14 years old, and adults also participated in the study. These adults came from 87 households, with 51 households supplying only one adult. There were 101 nonwhite children in the study population; of these 87% were of African-American descent.

Participant Characteristics

Participant characteristics differed by sampling region. Overall, 17% of the heads of households had not finished high school, 45% had graduated from high school, and 38% had education beyond high school. The education level achieved by the parents of children under 6 years of age with blood lead levels of ≥ 0.48 μmol/L (≥ 10 μg/dl) differed significantly from

parents with children under 6 years of age with blood lead levels of < 0.48 μmol/L (< 10 μg/dl) ($p < 0.001$). Among the heads of household whose children had blood lead levels ≥ 0.48 μmol/L (≥ 10 μg/dl), 35% had not finished high school, 42% had a high school diploma, and 23% had some higher education. For the heads of household with children with blood lead levels < 0.48 μmol/L (< 10 μg/dl), 14% had not finished high school, 46% had a high school diploma, and 40% had some higher education. Fifty-eight percent of the heads of households with children under 6 years of age with blood lead levels ≥ 0.48 μmol/L (≥ 10 μg/dl) had incomes of less than $15,000 per year. Only 41% of parents with children whose blood lead levels were < 0.48 μmol/L (< 10 μg/dl) were in this group. In the $15,000 to 25,000 income group, 24% had children with blood lead levels ≥ 0.48 μmol/L (≥ 10 μg/dl), while 22% had children with blood lead levels < 0.48 μmol/L (< 10 μg/dl). At income levels of $25,000 or above, 37% had children with blood lead levels < 0.48 μmol/L (< 10 μg/dl), while 18% had children with blood lead levels ≥ 0.48 μmol/L (≥ 10 μg/dl). This difference was statistically significant ($p < 0.01$). As income increased, the chance that a child in the family had an elevated blood lead level decreased; however, education was a better predictor of blood lead levels than income.

At least 1 smoker was present in 263 (68%) of the households. In 5% of the households, 6 or more smokers were present. The mean number of cigarettes smoked per household per day was 16, with a range of 0 to 88. A total of 341 (87.8%) of the 388 households had air-conditioning.

In households with air-conditioning, the average number of cigarettes smoked per day was 17.6, and in houses without air-conditioning, the average number of cigarettes smoked per day was 35.4 ($p < 0.01$). There were an average of 2.4 smokers, smoking a mean of 33 cigarettes per day, in households with children whose blood lead levels were ≥ 0.48 μmol/L (≥ 10 μg/dl), and an average of only 1.6 smokers per household, smoking a mean of 18 cigarettes per day, with children whose blood lead levels were < 0.48 μmol/L (< 10 μg/dl). This difference was also statistically significant ($p < 0.01$).

For the children under 6 years of age, the amount of time spent at home did not appear to affect blood lead levels. The time spent sleeping, playing outside, and playing on the floor were of some predictive value and were used in the regression analyses.

Clinical Laboratory Results

Blood and urine specimens were collected between August 23, 1991, and September 20, 1991. Results of blood lead analyses are given in Tables 4 through 6. The arithmetic mean blood lead levels for each age group were below 0.48 μmol/L (10 μg/dl), the current CDC level of concern[6]. Blood lead was measured in 490 children (261 males and 229 females) from 6 through 71 months of age. Figure 2 shows the distribution of the blood lead levels by year of age in the children under 6 years of age. As shown in Figures 2a through 2c, blood lead levels peaked in the children around 2 years of age and then gradually declined in older children to the same values observed in children around 1 year of age.

Blood lead levels were also determined in 214 youths (111 males and 103 females) aged 6 through 15 years and in 47 males and 76 females older then 15 years. Thus, 827 blood lead determinations were made in all. The arithmetic mean blood lead levels for the youngest age group (between 6 and 71 months of age) was 0.33 μmol/L (6.9 μg/dl), with a range of 0.03 to 1.94 μmol/L (0.7 to 40.2 μg/dl). In that group, 78 children (16%) had blood lead levels ≥0.48 μmol/L (≥10 μg/dl). For the children from 6 through 14 years of age, the arithmetic mean blood lead level was 0.21 μmol/L (4.4 μg/dl), the range was from <0.03 to 0.90 μmol/L (<0.6 to 18.8 μg/dl). In this group, eight children had blood lead levels of ≥0.48 μmol/L (≥10 μg/dl).

Among a total of 101 nonwhite children under 6 years of age, 87% were African-American. Of these children, 19% had elevated blood lead levels; the arithmetic mean for this group was 0.35 μmol/L (7.4 μg/dl). The arithmetic mean blood lead level of white children under 6 years of age was 0.32 μmol/L (6.8 μg/dl). Thus, the blood lead levels of African-American children were quite similar to those of white children (t = - 1.1; NS). These two groups of children were, therefore, combined in the analysis.

Among the children 6 years of age and older, 17 African-American boys and 16 African-American girls participated in the study. Their arithmetic mean blood lead levels were 0.20 μmol/L (4.2 μg/dl) and 0.23 μmol/L (4.7 μg/dl), respectively. None of these children had blood lead levels of ≥0.48 μmol/L (≥10 μg/dl).

The 43 white adult males had an arithmetic mean blood lead level of 0.28 μmol/L (5.8 μg/dl) and included 3 male adults with elevated blood lead levels. One of these 3 males had made lead sinkers, 2 were engaged in scrap metal recovery at home and wire cutting, and all 3 did auto body repair work at home. Their children, who were also exposed to high paint and soil lead, had elevated blood lead levels as well. The arithmetic mean blood lead level of 69 adult white females was 0.12 μmol/L (2.4 μg/dl). Among the 69 adult females, 14 were pregnant at the time blood specimens was drawn. Their blood lead levels ranged from <0.03 to 0.16 μmol/L (<0.6 to 3.4 μg/dl) with an average of 0.08 μmol/L (1.6 μg/dl). Three African-American adult males and 7 African-American adult females with arithmetic mean blood lead levels of 0.18 μmol/L (3.8 μg/dl) and 0.17 μmol/L (3.5 μg/dl), respectively, also participated in the study.

In the youngest age group, 78 (16% of total participants in this age group) had blood lead levels ≥0.48 μmol/L (≥10 μg/dl); however, 46 of these (9%) had blood lead levels from 0.48 to 0.72 μmol/L (10 to 15 μg/dl) and only 5 (1%) were above the pre-1991 CDC level of concern of 1.21 μmol/L (25 μg/dl) (Table 5). A total of 61 children with blood lead levels ≥0.48 μmol/L (≥10 μg/dl) and some of their siblings donated a second blood specimen in January of 1992 (Table 6), about 4 months after the initial collection, following extensive counselling of parents and children. The repeat blood lead levels of most of these 61 children were <0.48 μmol/L (<10 μg/dl) and had dropped to about half or more of their original value (Table 6). The highest blood lead level was 0.61 μmol/L (12.7 μg/dl). A subset of 30 children of this group of 61 children was retested about a year after the first testing. At the second

testing in January 1992, a mean blood lead level of 0.39 μmol/L (8 μg/dl) was found in this group. The mean blood lead level at the third testing (July, 1992) was 0.43 μmol/L (9 μg/dl) suggesting that, following the initial drop, the blood lead levels remained stable.

The data on complete blood counts (CBCs) of the children under six years of age are given in Tables 7 and 8. No difference in the CBCs is seen between the children with blood lead levels ≥0.48 μmol/L (≥10 μg/dl) and those with levels <0.48 μmol/L (10 μg/dl).

Among the youths 6 through 14 years of age, 8 white males had elevated blood lead levels. Four youths had blood lead levels of 0.48 μmol/L (10 μ/dl) and the other four had blood lead levels of 0.6, 0.6, 0.7, 0.9 μmol/L (12.6, 12.7, 13.8 and 18.8 μg/dl), respectively. All but one of the families involved had at least one smoker in the household. In three instances, work had recently been done on the residences. In three of the other households, the father worked at home on automobile bodies, was engaged in wire cutting and scrap metal recovery, cleaned and repaired fire arms, or was engaged in soldering and automobile radiator repair. Thus, in six instances repair work on the residence or work with metals at the residence could have contributed to exposure.

Urine Cadmium Analyses

Results of the urine analysis for cadmium showed that, in many specimens, cadmium was below the limit of detection of <0.1 μg/L. A total of 6 urine specimens contained cadmium at 2 μg/l or greater. Three urine specimens contained about 2 μg/L of cadmium. Additional urine specimens were collected from 3 other participants whose initial urine specimens contained cadmium at concentrations of ≥5 μg/L; however, the results of the reanalyses were below the limit of detection of 0.1 μg/L suggesting contamination of the initial sample.

Clinical Chemistry Tests

Urine specimens were tested for albumin, glucose, occult blood, and specific gravity, and were examined microscopically. Abnormal urine specimens were noted in one adult female and in six female children ranging in age from one to five years. These urine specimens were cloudy in appearance, and had white and/or red blood cells and bacteria. These findings appeared to be incidental and consistent with bladder infections.

Clinical chemistry tests were also performed on the blood specimens. The electrolytes potassium, sodium, and chlorides; the liver function tests aspartate aminotransferase (AST or SGOT), alanine aminotransferase (ALT or SGPT), gamma-glutamyl transpeptidase (GGT); total protein; albumin; blood urea nitrogen (BUN); and creatinine were measured. The electrolytes of all participants were within normal range. One child with a blood lead level of 0.42 μmol/L (8.9 μg/dl) had an elevated blood urea nitrogen of 50 mg/dl, while two additional children had levels just outside the reference range (6 to 26 mg/dl) of the clinical laboratory. The child with the elevated BUN also had elevated liver function test results, with an AST (SGOT) of 171 international units per liter (IU/L), a GGT of 103 IU/L, and an ALT (SGPT) of 68 IU/L.

Two other children under 6 years of age had elevated ASTs (SGOTs) of 437 and 83 IU/L. One child had an elevated GGT of 83 IU/L, and another had an elevated ALT (SGPT) of 472 IU/L. One youth had a slightly elevated ALT (SGPT) of 63 IU/L. Among the adults, four females had one or more slightly elevated liver function tests. The highest GGT was 75 IU/L, and the highest ALT (SGPT) was 61 IU/L. The AST (SGOT) was not elevated in any of the adult female or male participants. Abnormal liver function tests were present in six adult male participants. The highest GGT was 195 IU/L and the highest ALT (SGPT) was 83 IU/L. Immunoglobulin A and G were within the normal range in the study population according to Wallach[7]. Immunoglobulin M was elevated in 36 (4.4%) of the participants. Three of these participants had abnormal liver function test results as well. The elevated immunoglobulin M in participants with normal liver function test results was probably the result of a chronic infection. Since no clinical information was collected in this study, no definite interpretation of these results can be made.

Environmental Data

A total of 34% of all participants did not know the age of the house they were living in. Among the 412 children under 6 years of age with blood lead levels of <0.48 μmol/L (<10 μg/dl), data on the ages of the houses were available for 278. Of the children living in those houses, 196 (70%) lived in houses that were built before 1950. Of the 78 children with blood lead levels of ≥ 0.48 μmol/L (≥ 10 μg/dl) data on the ages of the houses they were living in was available for 43 houses. Of the children living in these 43 houses, 35 (81%) lived in houses built before 1950. Of the children with elevated blood lead levels who lived in the eight houses built after 1950, one child lived in a mobile home and the father was involved in lead-related activities. The remaining seven houses were built between 1950 and 1970 and remodelling activity or refinishing of furniture had taken place between 1990 and 1991.

Lead levels measured in the paint and soil of the houses are given in Tables 9a and 9b. Houses in which children with elevated blood lead levels lived were not clustered. However, those children were more likely to live closer to the smelter (Figure 1). Of the children under 6 years of age with blood lead levels <0.48 μmol/L (<10 μg/dl), 16% percent lived in sampling region 1, 43% in sampling region 2, 24% in sampling region 3, and 16% in sampling region 4. Among the children whose blood lead levels were ≥ 0.48 μmol/L (≥ 10 μg/dl) 27% lived in sampling region 1, 53% in sampling region 2, 12% in sampling region 3, and 8% in sampling region 4. Many of the children of both groups lived in houses with high paint lead concentrations in one or more of the areas measured (Table 9a). Either recent renovation or poor maintenance of the houses seemed to contribute to the exposure of the children. When the houses were in good condition, increased lead exposure was not as much of a problem.

Overall, about 50% of the families had done some repair work or renovations on their residences in 1990 or 1991. For families with children under 6 years of age whose blood lead levels were <0.48 μmol/L (<10 μg/dl), 48% had done some work on their house in the last year and 52% had not. In contrast, 63% of the families whose children had blood lead levels

were ≥ 0.48 μmol/L (≥ 10 μg/dl) had done some repair work in the year before the study, while 37% had not. The difference was statistically significant ($p < 0.02$).

In many yards, the lead concentrations in soil were above background levels, which in the United States can range from < 1 to 200 mg/kg (< 1 to 200 ppm). The mean soil lead level for the 375 analyzed soil samples was 450 mg/kg (450 ppm) with a range from 37 to 3,010 mg/kg (37 to 3,010 ppm) (Table 9b). A total of 39 duplicate (split) samples were also analyzed. These duplicate samples were homogenized and divided in the field. The analyzing laboratory was unaware of the fact that they were duplicates. The concentration of lead in these duplicate soil samples ranged from 106 to 1,610 mg/kg (106 to 1,610 ppm). The average difference between the 39 primary and the 39 duplicate samples was 89 mg/kg (89 ppm).

It is evident from Tables 9a and 9b that there were some very high environmental lead values. For example, the minimum dust lead value was 5.2 mg/kg (5.2 ppm) while the maximum value was 71,000 mg/kg (71,000 ppm). The standard deviation was nearly four times as great as the mean. Most of the other data were also not normally distributed. Log-transformed data was, therefore, used for most of the statistical analyses.

A total of 375 composite soil samples were also analyzed for cadmium. The arithmetic mean cadmium concentration in soil was 3.1 mg/kg (3.1 ppm) with a standard deviation of 1.37. Cadmium was not detected in 8 soil samples at a limit of detection of 1.0 mg/kg (1.0 ppm) and all but 7 soil samples were < 6 mg/kg (< 6 ppm). The background concentrations of cadmium in soil generally found in other studies ranges from 0.3 to 11 mg/kg (0.3 to 11 ppm) according to Page and Bingham[8] and Lund et al.[9]. Thus, cadmium concentrations were within the background range of concentrations found by others.

Lead in drinking water was below the limit of detection of the analytical method of 2.0 μg/L (2.0 ppb) in 62% of the samples from 373 households. A total of 86% of the samples had levels ≤ 5 μg/L (≤ 5 ppb) and 97% were < 15 μg/L (< 15 ppb), the present USEPA action level. In 13 instances, levels of lead in drinking water were higher, with a range from 15.4 to 95.5 μg/L (15.4 to 95.5 ppb). However, study participants using this water did not have elevated blood lead levels. The correlation between the log water measure and log blood lead was very low ($r = 0.07$, NS).

Of 373 drinking water samples, the concentrations of cadmium in 322 drinking water samples were below the limit of detection of ≤ 0.5 μg/L (≤ 0.5 ppb). The maximum concentration detected in any water sample was 9.9 μg/L (9.9 ppb). Only 11 samples were > 2 μg/L (> 2 ppb). In a survey of 969 community water supply systems in the United States, the average cadmium concentration was 1.3 μg/L (1.3 ppb) according to Craun and McCabe[10] which did not differ from the findings in this study. Furthermore, all of the measurable concentrations in our study were in compliance with the federal drinking water standard of 10 μg/L (10 ppb) for cadmium.

Levels of lead in dust are also listed in Table 9b. They varied widely, both on a weight basis in mg/kg (ppm) (the concentration of lead in dust) and on the amount of lead present on a given surface area, (the loading of dust with lead) in $\mu g/m^2$. Among all environmental measures, dust load (the amount of lead in dust based on surface area) was the best predictor of blood lead levels in small children. The log dust load was the highest Pearson correlation of any variable with blood lead levels ($r = 0.42$, $p < 0.0001$).

Bivariate Analyses

Although bivariate analyses ignore the effects of possible confounding or effect modification from the influence of other variables, they provide a simple first screening of the complex relationships among the many variables in this study. Since bivariate analysis can not be used to adjust for possible confounding, this type of analysis greatly oversimplifies the true nature of relationships among the variables. For this reason, bivariate analysis results can not be interpreted out of context. They also do not constitute evidence of causal relationships. However, detailed inspection of the large matrix of bivariate results produced by pairwise analyses of key variables can reveal patterns of relationships that can then be explored by more appropriate multivariate analysis.

Soil Lead, Comparing Levels ≥500 mg/kg (≥500 ppm) with Lower Levels

A total of 143 children under 6 years of age lived in houses with composite soil samples of ≥500 mg/kg (≥500 ppm) lead and 347 children in the same age group lived in houses with soil lead levels <500 mg/kg (<500 ppm). Comparisons between these two groups identified differences in blood lead levels, dust lead levels, indoor and outdoor paint lead levels, the number of cigarettes smoked per day in the house, and the age of the houses. However, the differences were very small for blood lead levels, even though they were statistically significant. The geometric mean blood lead level of children living in houses with soil lead levels of ≥500 mg/kg (≥500 ppm) was 0.32 μmol/L (6.6 μg/dl) compared with 0.25 μmol/L (5.2 μg/dl) for children living in houses with soil lead levels <500 mg/kg (<500 ppm) ($p < 0.01$). The differences were larger for other measured parameters. The geometric mean dust load in houses with soil lead levels ≥500 mg/kg (≥500 ppm) was 400 $\mu g/m^2$, compared with 100 $\mu g/m^2$ in houses with soil lead levels <500 mg/kg (<500 ppm) ($p < 0.01$). The mean lead concentration in dust on a weight basis was 780 mg/kg (780 ppm) for houses with soil lead levels ≥500 mg/kg (≥500 ppm) and 309 mg/kg (309 ppm) for houses with soil lead levels <500 mg/kg (<500 ppm) ($p < 0.01$). The geometric mean indoor paint lead level in houses with soil lead levels ≥500 mg/kg (≥500 ppm) was 1.4 mg/cm^2 compared to 0.5 mg/cm^2 for houses with soil lead levels <500 mg/kg (<500 ppm) ($p < 0.01$). The geometric mean outdoor paint lead level in houses with soil lead levels ≥500 mg/kg (≥500 ppm) was 8.6 mg/cm^2 compared with 3.0 mg/cm^2 in houses with soil lead levels <500 mg/kg (<500 ppm) ($p < 0.01$). In houses with soil lead levels ≥500 mg/kg (≥500 ppm), 25.5 cigarettes per day were smoked compared with 17.9 cigarettes smoked per day in houses with soil lead levels <500 mg/kg (<500 ppm) ($p < 0.01$). Houses with soil lead levels ≥500 mg/kg (≥500 ppm) were, in general, built sometime during the period 1920 through 1929, while houses with soil lead

levels <500 mg/kg (<500 ppm) were usually built sometime during the period 1940 through 1949.

Blood Lead

All of the following blood lead correlations are statistically significant at $p<0.01$: lead in indoor paint, $r = 0.16$; composite soil lead, $r = 0.25$; dust lead level, $r = 0.25$; dust load, $r = 0.42$; distance of the house from the closed lead smelter, $r = 0.26$; parents' education, $r = -0.29$; parents' income, $r = -0.26$; number of smokers in the household, $r = 0.16$; number of cigarettes smoked per day in the residence, $r = 0.23$; number of hours played outdoors, $r = 0.23$; and number of baths taken per week, $r = 0.21$.

In addition, the following categorical variables were associated ($p<0.01$) with blood lead when children with high (≥ 0.48 μmol/L [≥ 10 μg/dl]) and low (<0.48 mol/L [<10 μg/dl]) blood lead levels are compared: air-conditioning present/absent; renting versus owning the residence; condition of the residence; and refinishing of the residence or furniture ($p<0.02$).

With so many correlates of blood lead, it is clearly not possible to draw causal inferences without first considering how all of these blood lead predictor variables can influence one another, and confound their relationships with blood lead.

Soil Lead

The most important confounder of the relationship between soil lead and blood lead is the high degree of correlation between composite soil lead and lead in indoor paint, $r = 0.34$. Other correlates of composite soil lead are house dust load, $r = 0.43$; distance from the smelter, $r = -0.48$; education, $r = -0.11$; income, $r = -0.11$ ($p<0.02$); cigarettes per day, $r = 0.17$; and year the house was built, $r = -0.45$. All correlations are statistically significant at $p<0.01$ unless otherwise noted.

Distance

In the study population, distance from the closed lead smelter was a correlate of blood lead ($r = -0.26$; $p<0.01$). It is tempting to think of distance as a proxy for soil lead exposure because distance was correlated with composite soil lead ($r = -0.48$; $p<0.01$). However, the relationship of distance, composite soil lead, and blood lead was confounded by other variables. Distance was negatively correlated with the number of smokers ($r = -0.24$; $p<0.01$) and the number of cigarettes smoked per day in the house ($r = -0.30$; $p<0.01$). The year the participant's residence was built correlated with distance ($r = 0.16$; $p<0.01$). The older houses were closer to the smelter. The parents' education level ($r = 0.16$; $p<0.01$) and income ($r = 0.18$; $p<0.01$) correlated with distance. The condition of the houses improved with distance from the smelter (chi-square = 440.0, df = 6; $p<0.01$) and the use of air-conditioning increased (chi-square = 10.8, df = 1; $p<0.01$). As distance increased, dust lead decreased ($r = -0.21$; $p<0.01$.) while home ownership increased (chi-square = 14.3, df = 3; $p< 0.01$).

All of these correlates of distance were also associated with one another, and were among the better predictors of blood lead in this study.

Building Condition

Building condition was significantly associated with the following variables ($p < 0.01$, except as noted): the number of cigarettes smoked per day; indoor and outdoor paint lead levels, soil lead levels, water lead levels ($p < 0.08$), and dust lead levels; parents' education level, and parents' income; hours of outdoor play; and the number of baths per week ($p < 0.03$). Each variable increased steadily over the three levels of building condition, with the exception of water lead levels.

Building condition was one of the better predictors of blood lead in this population. The mean blood lead level of children living in residences in good condition was 0.29 μmol/L (6 μg/dl). Children living in houses in fair condition had a mean blood lead level of 0.4 μmol/L (8.2 μg/dl) and children living in residences in poor condition had a mean blood lead level of 0.57 μmol/L (11.8 μg/dl). The condition of the house influenced its dust load (a measure that combines dust level and lead concentration). The dust load was seven times higher in residences in poor condition than in houses in good condition and about three time higher in residences in fair condition. Building condition was also relatively highly associated with every other predictor of blood lead in this study, and was a confounder in the relationship of composite soil lead and blood lead. Houses in good condition had a mean soil lead concentration of 287 mg/kg (287 ppm). The mean soil lead concentration for houses in fair condition was 361 mg/kg (361 ppm), and for houses in poor condition was 459 mg/kg (459 ppm). Building condition differed from other potential confounders of the composite soil lead/blood lead association in that the condition of the house was not likely to be a pathway for soil lead exposure. It was one of the few confounders of the soil lead/blood lead relationship that could be controlled for statistically.

Cigarettes Per Day

In this data set, smoking was associated with blood lead. The number of smokers ($r = 0.16$; $p < 0.01$), and the number of cigarettes smoked per day ($r = 0.23$; $p < 0.01$), both predicted blood lead levels to some extent. However, while the number of cigarettes smoked per day was also correlated with dust load ($r = 0.15$; $p < 0.01$), it was not correlated with the dust level (that is, the weight of the dust sample divided by the area vacuumed $r = 0.005$; $p = 0.92$). The number of cigarettes smoked per day was also correlated with composite soil lead ($r = 0.17$; $p < 0.01$), distance from the smelter, parents' education level ($r = -0.34$; $p < 0.01$), income ($r = -0.20$; $p < 0.01$), and outdoor paint lead levels ($r = 0.11$; $p < 0.02$). Furthermore, smokers in residences without air-conditioning smoked an average of 35.4 cigarettes per day, while smokers in residences with air-conditioning smoked 17.5 cigarettes per day ($t = -3.8$; $p < 0.01$) on average. More cigarettes were smoked in houses in poorer condition ($r = 17.2$, $df = 2$, $p < 0.01$) and in older houses ($r = 0.16$; $p < 0.01$). It was not possible to determine whether cigarette smoke made any independent contribution to

blood lead in passive smokers, or was simply a proxy for other environmental, socioeconomic, and behavioral factors. Other authors have reported such a contribution[11], although in a later paper they were unable to confirm their findings[12].

Regression Analysis

Because of the many variables in this study expressed as continuous measures, regression analysis provided the best method of analysis. The advantages of regression analysis in this instance were twofold: the ability to simultaneously analyze many variables and the ability to observe the influence of each variable on every other variable. Since in this study interrelationships among the variables are complex, regression analysis may be the only way to express the many relationships[5].

Stepwise Regression

Once the list of potential predictor variables was narrowed, the maximum R^2 improvement method was used to select and assign priority to the most important predictors. The first variable was dust lead ($R^2 = 0.17$), accounting for about 17% of the total blood lead variance; second was distance, raising R^2 to 0.21; third was parents' education level, raising R^2 to 0.24; finally distance, education, refinishing activities, hours of outside play, and participant's age all traded places in and out of the model for several more steps, bringing R^2 to 0.32. Ethnicity and lead in drinking water raised R^2 to 0.35.

It is noteworthy that neither ethnicity nor lead in drinking water were significantly associated with blood lead levels in bivariate tests. The fact that they entered the regression ahead of more obvious measures indicated that these two variables might have been serving as proxies for other exposures, or that they did not share with other variables any of the variance in blood lead that they accounted for individually.

As shown in Table 10, with 10 variables in the regression model, R^2 reached 0.37. These variables represented parents' education level, the number of cigarettes smoked per day, rent/own home, refinishing activities, ethnicity, dust load, age, water lead levels, distance, and the number of hours of outdoor play per day. Apparently, variations in individual behavior accounted for most of the remaining blood lead variance in this group. Errors in lead measurements were probably of secondary importance in explaining the blood lead variance not accounted for. While the preceding approach gives some idea of the role of different variables as predictors of blood lead, the value of the approach is limited. Since this method capitalizes on chance, the statistical p-values associated with partial regression coefficients could not be interpreted. The hierarchical regression modeling that follows focuses specifically on the contribution of paint and soil lead to blood lead.

Hierarchical Regression: The Contribution of Soil Lead to Blood Lead

The intercorrelation among independent variables in this study, and their correlations with both soil lead and blood lead, suggested that the association of soil lead with blood lead was confounded to some extent by other factors in the study. To assess the independent contribution of soil lead to blood lead, it would have been desirable to control statistically for potential confounding through hierarchical regression. First, the set of variables that might have confounded the relationship of soil lead and blood lead could have been introduced, and then the soil lead variable to evaluate the increment in blood lead variance accounted for by soil lead levels. However, in order to avoid over-adjusting (that is, inappropriately removing variance in blood lead that could be due to soil lead exposure), a very limited set of potential confounders was used. House dust was an important secondary source of lead exposure in young children. However, house dust was not included as a potential confounder since the source of lead in dust was mostly paint and soil. Thus, house dust represented a vector, or pathway, for the two primary sources of lead: soil and paint.

As shown in Table 11, Model 1; water lead levels, house paint lead levels, recent household refinishing activities, and the rating of the overall condition of each building (that is, the general state of repair/disrepair of the residence) accounted for 11% of the blood lead variance in this study (adjusted $R^2 = 0.11$). These were the only potential confounders of the soil lead/blood lead relationship that were statistically controlled. When composite soil lead measures were added, as shown in Table 11, Model 2, the adjusted R^2 increased only slightly to adjusted $R^2 = 0.14$. Thus, only 3% of the variance in blood lead observed in the study population was accounted for by soil lead.

The Contribution of Soil Lead to Dust Lead

As shown in Table 12, Model 1; indoor and outdoor paint lead levels, and the condition of the building accounted for 26% of the variance in dust lead. When composite soil data were added (Table 12, Model 2), R^2 increased to 0.32, an increase of 6% in dust lead variance. Thus, paint lead levels and building condition accounted for about four times as much variance in dust lead as did soil lead.

Effect of Including More Than One Child Per Family in Analyses

Using all of the children in each family, or only the child with the highest or lowest blood lead level in the various analyses did not affect outcome (Table 13). The conditions of the houses and the concentrations of lead in soil, paint, and dust were quite similar among families with one child or more than one child under 6 years of age. The distances of the houses from the closed smelter were similar as well. The participants rather than the households were, therefore, used in most statistical analyses.

DISCUSSION

This study was primarily undertaken to determine whether children, under the age of six years, living in an environment with elevated lead levels in soil had elevated blood lead levels. Results showed that, in addition to lead in soil, other sources of high lead levels (for example, indoor and outdoor paint) in residences also existed in the community.

It was not possible to find, in the vicinity of the study area, a separate community of similar socioeconomic makeup and housing stock with no history of high soil lead concentrations. Therefore, the residents of areas without high concentrations of lead in soil adjacent to the NPL declaration area were used as the comparison population. Although this control population lived in houses of similar age and with similar concentrations of lead in paint, some other differences existed. As distance from the smelter increased, the conditions of the houses improved; fewer houses had peeling paint and most houses were owned rather than rented. Furthermore, the education level of the parents increased, the number of smokers and the amount of smoking decreased, the use of air-conditioning increased, and other behavioral variables also changed with distance. As anticipated, the concentration of lead in soil also decreased with distance from the closed smelter. The covariance of risk factors with distance from the smelter made it more difficult to interpret and analyze study results. The study showed that lead exposure risk factors do not occur in isolation. Most of the important lead exposure risk factors occur in and around poorly maintained houses.

The participation rate in this study was not optimal. However, as many people living close to the smelter as living further away were included in the study. If anything, the participation rate closer to the closed smelter was better. Thus, if high levels of lead in soil were a prominent factor of exposure, a soil effect would more likely be detected.

In this particular population the primary exposure of concern was the exposure of young children to lead. It has been documented in many studies that children, because of their hand-to-mouth activities, ingest lead primarily through dust; however, they may also ingest paint chips and soil that contain lead. In addition, children are exposed to lead through food, water, and air. How much environmental lead a child will receive from these various sources depends on many behavioral variables and also on the child's nutrition[3].

This study details a number of interesting findings, the most important of which was that most study participants had comparatively low blood lead levels. This is consistent with results obtained by others in recent surveys. Blood lead levels in the population as a whole and in young children are now much lower than they were one or two decades ago[13]. The decrease in blood lead levels has resulted from the reduction of lead in gasoline and the decreased use of leaded gasoline. Lead in food, particularly in infant food, has also been reduced[14]. Lead levels in children in many communities are now around 0.25 μmol/L (5 μg/dl) or less. In this study, the mean blood lead levels were consistent with these observations.

In spite of elevated lead levels in soil and in indoor and outdoor paint, many children had very low blood lead levels. Even the group with elevated blood lead levels had mean blood lead levels that 20 years ago were representative of small children in the general population and were mostly below the CDC level of concern (1.21 μmol/L [25 μg/dl]) for elevated blood lead levels in effect until recently. In the National Health and Nutrition Evaluation Survey (NHANES II)[15] conducted from 1976 through 1980, the arithmetic mean blood lead levels for young children were 0.7 to 0.97 μmol/L (15 to 20 μg/dl)[13] after high outliers had been removed. Most of the elevated blood lead levels in this study are lower than the NHANES II levels. At blood lead levels >1.21 μmol/L (>25 μg/dl), determination of erythrocyte protoporphyrin (EP or ZPP) is not useful since it will be normal in most cases[16]. EP measurements were, therefore, not made. The findings in this study suggest that, once the major sources of high levels of lead in air and in food have been removed, high lead levels in soil and in paint might make less of a contribution to overall lead exposure than previously assumed. However, lead uptake is largely influenced by individual factors of behavior, such as improper renovation of old houses, pica, or poorly maintained residences.

As a predictor for blood lead level, the education level of the parents was more important than income. Smoking, remodelling or other repair of the residence, lead levels in paint and soil, and the age of the house were all positively correlated with blood lead levels. Education level and income were inversely correlated with proximity to the closed smelter.

Blood lead measures in children were used as the dependent variable in a series of regression analyses designed to interpret the contributions made by selected independent variables. The independent variables were grouped differently depending upon the question under investigation. To the extent that these variables predicted blood lead levels and were also correlated with soil lead, they should be considered to represent confounders of the relationship of blood lead and soil lead.

Some measures are clearly influenced by both soil lead and paint lead. House dust lead is a mixture of soil lead and house paint lead. House dust is actually an important secondary source of lead for young children because of their hand-to-mouth activities. Lead in house dust comes primarily from soil and from paint and represents a vector or pathway for lead exposure. House dust was, therefore, not included in the hierarchical regression against blood lead. The apparent contribution of soil and paint would have been overadjusted had this been done. Furthermore, simultaneous regression of all three factors against blood lead levels resulted in a related problem, multi-colinearity. Simultaneous regression of lead in paint, lead in soil and lead in dust against blood lead would have produced unpredictable and invalid partial correlation coefficients.

The number of hours spent at home and the number of hours spent outside, the age and sex of the child, and most behavioral variables can serve as predictors of exposure for paint and soil lead. Using these variables to make statistical adjustments is not likely to resolve problems of confounding, and might introduce additional problems of overadjustment.

A number of variables predicted blood lead levels in young children. These included the condition of the residence; lead levels in paint, in dust, and in soil; smoking in the residence; proximity to the closed smelter; education and income levels of the parents; and behavioral factors of the children, such as hand-to-mouth activities. Comparing these factors showed that they were all correlated with each other. Only about 40% of the exposure could be accounted for in the data analyses. Of this 40%, lead from soil appeared to make a very minor contribution, at most 3%, while the condition of the house and the amount of lead in paint may have been responsible for as much as 11%. The percent of the variance reflects the degree of importance a given environmental factor has for the total exposure of the child. Eliminating a variable such as soil that accounted for only 3% of the variance may only result in a minimal change in measured blood lead levels without any clinical significance.

The large unaccounted portion of lead exposure (60%) is partly attributable to lead in food, ambient air, imprecision in the blood and environmental lead measurements, changes of the dust load and unique variables in specific households. For instance, in addition to high lead concentrations in soil and in paint in one family's home, the father made lead sinkers, worked on automobile bodies and salvaged metal at home. Dust was also only collected at one point in time. A one time dust sample may not be representative for the dust over a period of several months.

Most of the important variables in this study (such as the education and income levels of the parents; lead levels in paint, soil, and dust; behavior variables; smoking; and air-conditioning) were all highly correlated. Thus, correlations, t-tests, and chi-square tests, if taker out of context could be misleading. Furthermore, confounding could not be adequately controlled for in this data set. House dust serves as a pathway of exposure for soil lead and house paint lead in small children. Many important behavioral variables could affect the degree of exposure to house dust. Small but statistically significant differences in the percent variance have no clinical importance as far as their potential contribution to blood lead levels is concerned. This study attempted to determine, by stepwise regression of 22 variables, the overall contribution of these variables to lead exposure. However, as some variables were added to the analyses, other variables dropped out and variables that had previously dropped out were in the regression again. This suggested that some of the variables were also proxies for other variables and that they did not constitute meaningful contributions to the exposure of small children.

Since most of the youths and adults had very low blood lead levels, we concentrated our evaluation on the children under 6 years of age. In the older age group, the few participants with elevated blood lead levels acquired their lead through hobbies, occupation pursued by themselves or family members, or repair of their residences. No detailed statistical analyses were conducted on this group, since the number of affected individuals was small and their elevated blood lead levels had individual, logical explanations.

An important and often ignored method of preventing lead exposure is education about effective ways of reducing exposure and increasing awareness and understanding among

parents/guardians. Following extensive counselling of the parents/guardians of children with blood lead levels ≥ 0.48 μmol/L (≥ 10 μg/dl) about pathways of lead exposure for children, the follow-up blood lead determinations showed a marked and persistent decline in blood lead levels. In the past, seasonal fluctuations in children's blood lead levels have been reported with principal emphasis on the summer peak[17,18]. However, Marrero et al.[19] reported two peaks, one in late winter, and one in midsummer. Marrero et al.[19] found the low levels to be at most about a third less than the peak value. Our initial blood lead level determinations were made in late August and in September when the midsummer peak had already been passed.

The seasonal fluctuations observed many years ago were closely associated with the sale of leaded gasoline, fluctuations in lead air levels, weather patterns, traffic density[20], and outdoor activity. Since lead in gasoline has been reduced, seasonal variation is less of an issue now. However, children's blood lead levels also decrease as the children get older. In a recently published study to determine the effect of soil and interior loose paint removal on blood lead levels, the mean decline in blood lead levels between preabatement and 11 months after abatement was 0.12 μmol/L (2.44 μg/dl) in children under 6 years of age with blood lead levels quite similar to the blood lead levels in this study in children of similar age. Loose paint removal per se only resulted in a drop of 0.02 μmol/L (0.52 μg/dl)[21]. These differences are very small in comparison to our findings. Fluctuations in blood lead levels are also affected by the analytical method that must be very accurate, precise and free of drift over time.

Blood lead levels fluctuate somewhat if repeated samples are taken. This fluctuation can occur because of variations in the analytical method[22]. Lead levels in capillary blood specimens are usually higher than in venous blood specimens. Venous blood samples provide more accurate results and are preferred by health care providers although parents may be reluctant to submit their children to venipuncture.

Not all of the parents invited to participate in the study accepted the invitation. A primary reason for refusal was the unwillingness of parents/guardians to have blood specimen drawn from their children because of the emotional trauma associated with the event. Parents/guardians need to be educated on the importance of such testing and of preventing excessive exposure to lead. Based on the findings in this study, two years of age would be the optimal age for testing, since blood lead levels seemed to peak at that age.

CONCLUSIONS

1. Blood lead levels of children under 6 years of age and in older children and adults were, for the most part, below the new level of concern of 0.48 μmol/L (10 μg/dl).

2. In the study population, the highest percentage of children with elevated blood lead levels were from 1.5 through 2.5 years of age suggesting that this could be an optimal age for screening.

3. Children with higher blood lead levels lived in houses near the closed smelter, but they also lived in houses further away from the site, and as of 1991, outside the USEPA area targeted for soil clean up.

4. The soil lead levels decreased as distance from the smelter increased.

5. For small children, house dust served as a major vector of exposure. The source of lead in house dust was the lead in paint and soil.

6. High concentrations of lead in paint in well-maintained houses did not contribute noticeably to lead exposure. Many of the children with low blood lead levels lived in houses in good condition, but with very high lead paint levels.

7. Lead uptake was influenced by many personal variables (such as behavior, socioeconomic status, education, smoking), and variables present in each house. These individual factors were difficult to assess. The inability to account for 60% of the variance in lead uptake underscores that point.

8. Education of the parents/guardians about the lead hazards in their homes, suggestions for remedial action, and changes in behavior had a favorable impact on children's blood lead levels.

9. Lead in water, lead in paint, condition of the house, refinishing of the house within the last year, and lead in soil made statistically significant contributions to the variance in blood lead levels. However, the model using a hierarchical regression analysis was only able to explain 15% of the variance in children's blood lead levels.

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ABBREVIATIONS OF UNITS AND MEASURES

g/dl	= grams per deciliter
IU/L	= international units per liter
km	= kilometer
mEq/L	= milliequivalent per liter
mg/cm^2	= milligram per square centimeter
mg/kg	= milligram per kilogram
mg/dl	= milligram per deciliter
mg/cm^2	= milligram per square centimeter
ppb	= parts per billion
ppm	= parts per million
$\mu g/L$	= microgram per liter
$\mu g/dl$	= microgram per deciliter
$\mu g/m^3$	= microgram per cubic meter
$\mu mol/L$	= micromole per liter

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TABLES

Table 1.—Biomedical tests (blood and urine).

Test	Reference Range*		Expected Coefficient of Variability*
AST (SGOT)†	0-6 mo	0-120 IU/L	5.41
	7-12 mo	1-110 IU/L	
	1-5 mo	0-75 IU/L	
	6-10 yr	0-60 IU/L	
	>10 yr	0-50 IU/L	
ALT (SGPT)§		0-50 IU/L	8.33
GGT¶	Male	0-65 IU/L	6.45
	Female	0-45 IU/L	
Albumin		3.5-5.5 IU/L	2.78
Total Protein	Newborn	4.6-7.2 g/dl	3.23
	<2 yr	5.7-8.2 g/dl	
	≥2 yr	60.0-8.5 g/dl	
Creatinine		0.5-1.5 mg/dl	4.76
BUN**		7-26 μg/dl	7.14
Sodium		135-148 mEq/L	1.43
Potassium		3.5-5.5 mEq/L	2.44
Chloride		94-109 mEq/L	1.98

*Provided by the testing laboratories: IU/L = international units/liter; g/dl = grams/deciliter; mg/dl = milligrams/deciliter; μg/dl = microgram/deciliter; mEq/L = milliequivalent/liter.
†Aspartate aminotransferase (SGOT).
§Alanine aminotransferase (SPGT).
¶Gamma-glutamyltransferase.
**Blood urea nitrogen.

Table 2.—Study population household census data.

Census forms with address	5,734
Households indicating occupancy	5,134
Households with at least one child < 6 yrs of age	906
Disqualified households (moved, Pontoon Beach)	116
Target households	790
Refused to participate	266
Participating households with no child < 6 yrs of age	33
Households unaccounted for (no contact, no show)	169
Total households in study sample	388

Table 3.—Household* participation by target sampling region.

Sampling area 1 (closest to Taracorp)	39 target households 20 (51%) households participated
Sampling region 2	201 target households 120 (60%) households participated
Sampling region 3	242 target households 128 (53%) households participated
Sampling region 4 (farthest from Taracorp)	308 target households 120 (39%) households participated

*Thirty-three participating households did not have a child under six years of age at the time of testing, or no blood was obtained from that child.

Table 4.—Distribution of blood lead levels (BPbs) by age of participant*.

Age of Participant	6-71 Months	6-15 Years	>15 Years	Total
Total number	490	214	123	827
Male	261	111	47	419
Female	229	103	76	408
Mean BPb** μmol/L μg/dl	0.33 6.9	0.21 4.4	0.17 3.6	0.28 5.8
Range BPb μmol/L μg/dl	0.03 - 1.94 0.7 - 40.2	<0.03 - 0.90 <0.6 - 18.8	<0.30 - 0.86 <0.6 - 17.9	<0.03 - 1.94 <0.6 - 40.2
≥0.48 μmol/L (10μg/dl)	78	8	3	89

*Nine children included in this table lived at their present residence less than 3 months at the time of the study.
**BPb = blood lead.

Table 5.—Distribution of blood lead levels in children from 6 months to 6 years of age with blood lead levels ≥0.48 μmol/L (≥10 μg/dL).

Blood Lead Level	Number	Percent of Total 490 Children
≥0.48 μmol/L (≥10 μg/dl)	78	16
≥0.48 μmol/L and <0.72 μmol/L (≥10 μg/dl and <15 μg/dl)	46	9
≥0.72 μmol/L and <1.21 μmol/L (≥15 μg/dl and <25 μg/dl)	27	5.5
≥1.21 μmol/L (≥2.5 μg/dl	5	1

Table 6.—Comparison of original blood lead determination with 4-month follow-up lead level determination in 61 participants*.

Age	N	First Lead Range†	First Mean Lead†	Second Lead Range†	Second Mean Lead†	Range of Difference†	Mean Difference†
6-71 months	51	0.48-1.69 (10-35)	0.72 (15)	0.17-0.61 (4-13)	0.38 (7.8)	0.14-1.16 (3-24)	0.35 (7.2)
6-15 years	7	0.48-0.92 (10-19)	0.63 (13)	0.27-0.44 (6-9)	0.35 (7.3)	0.14-0.48 (3-10)	0.28 (5.9)
>15 years	3	0.58-0.87 (12-18)	0.68 (14)	0.27-0.47 (6-10)	0.36 (7.4)	0.3-0.4 (6-8)	0.34 (7.0)

*Seventeen participants either refused to be followed up or were lost to follow-up.
†Ranges, means, and differences are given in μmol/L and in (μg/dl).

Table 7.—Complete blood counts (CBCs) for 388 children 6 months to 6 years of age with blood lead levels < 0.48 μmol/L (< 10 μg/dl)*.

Complete Blood Counts	Mean	Range
White blood cells	8,332/mm^3	3,400-18,400/mm^3
Hemoglobin	12.2 g/dl	90.0-14.5 g/dl
Hematocrit	36%	25.6-41.7%
Red blood cells	4.4 x 10^6/mm^3	3.2-5.5 x 10^6/mm^3

*CBCs were not done for 22 children because insufficient blood was available.

Table 8.—Complete blood counts (CBCs) for 75 children* 6 months to 6 years of age with blood lead levels ≥ 0.48 μmol/L ($\geq 10/\mu$g/dl).

Complete Blood Counts	Mean	Range
White blood cells	9,116/mm^3	5,000-17,600/mm^3
Hemoglobin	12.3 g/dl	80.0-14.7 g/dl
Hematocrit	36%	26.6-42.8%
Red blood cells	4.5 x 10^6/mm^3	3.7-5.3 x 10^6/mm^3

*Three children did not have CBCs done because insufficient blood was available.

Table 9a.—Results from x-ray fluorescence readings of lead in paint.

Location of Reading	Houses Tested	Houses with >6 mg/cm^2 Lead (%)
Indoor paint*	372	154 (40.8)
Outdoor paint†	380	193 (51.0)
Indoor and outdoor paint	371	111 (30.1)

*Thirty percent of the houses had readings <1 mg/cm^2 and 29% had readings from 1 to 6 mg/cm^2.

†Twenty-two percent of houses had readings <1 mg/cm^2 and 27% had readings from 1 to 6 mg/cm^2

Table 9b.—Lead in environmental samples: soil, dust, and water.

Environmental Sample	N	Mean Lead	Minimum	Maximum	Standard Deviation
Soil-dry composite	375	450	37	3,010	411
Dust by weight (mg/kg)	371	1,283	5.2	71,000	5,236
Dust by surface ($\mu g/m^2$)*	367	885	1.6	58,800	4,489
Tap water $\mu g/L$ (ppb)	373	3.3	<2	96	8
Indoor paint (mg/cm^2)†	372	1.2	0	10.4	1.6
Outdoor paint (mg/cm^2)†	380	5.3	0	31.2	6.4

*The "dust load" was calculated by dividing the dust sample weight by the surface area vacuumed and multiplying this ratio by the dust lead concentration.

†The paint values represent means of 18 indoor and 12 outside readings. Readings of zero were included in the calculations.

Table 10.—Stepwise regression analysis, dependent variable: blood lead level in children from 6 months through 71 months of age.

$R^2 = 0.37$	F = 21.61; (Prob > F = 0.0001)			
Variable	Parameter Estimate	Standard Error	F Statistics*	Prob > F
Intercept	2.88	0.28	106.77	0.0001
Years of education	-0.04	0.01	5.98	0.0149
Cigarettes per day	0.00	0.00	4.57	0.0331
Rent or own home	-0.12	0.05	4.52	0.0342
Recent remodeling	-0.17	0.05	9.89	0.0018
Ethnicity	0.20	0.05	12.45	0.0005
Log of "dust load"	0.13	0.01	59.16	0.0001
Age	-0.08	0.01	20.29	0.0001
Log of lead in water	0.09	0.03	7.81	0.0055
Distance	-0.05	0.01	10.28	0.0015
Hours of outdoor play	0.06	0.01	24.13	0.0001

*F is the ratio of the regression mean squares over residual mean squares.
$F = R^2 (n - k - 1) / (1 - R^2) k$. The distribution of the F statistic is used to test the significance of R in regression analysis (that is to test the null hypothesis that the linear relationship between a set of k independent variables and a dependent variable is zero in the population).

Table 11.—Hierarchical regression analysis, dependent variable: log blood lead in children from 6 months through 71 months of age.

MODEL 1

Adj R^2 = 0.12; N = 433; Potential confounders P < 0.0001			
Variable	Parameter Estimate	Standard Error	P <
Intercept	1.54	0.11	0.0001
Log of lead in water	0.03	0.02	0.15
Log of CXI*	0.04	0.02	0.03
Log of CXO*	-0.01	0.01	0.6
Condition of residence†	0.34	0.05	0.0001
Refinish	-0.17	0.06	0.006

MODEL 2

Adj R^2 = 0.15; N = 433; Potential confounders and log soil			
Variable	Parameter Estimate	Standard Error	P <
Intercept	0.58	0.23	0.03
Log of lead in water	0.03	0.02	0.2
Log of CXI*	0.03	0.02	0.2
Log of CXO*	-0.01	0.01	0.2
Condition of residence†	0.3	0.05	0.0001
Refinish	-0.16	0.06	0.01
Soil composition	0.17	0.04	0.0001

*Log of CXI, Log of CXO are the logarithms of the sum of indoor and outdoor lead paint measurements multiplied by ratings of the condition of the paint where each XRF reading was made.

†Condition of residence is the rating of the overall state of repair/disrepair of the house.

Table 12.—Hierarchical regression analysis, dependent variable: log "dust load".

MODEL 1

Adj R^2 = 0.26; N = 433; Potential confounders			
Variable	**Parameter Estimate**	**Standard Error**	**P <**
Intercept	-2.47	0.16	0.0001
Log of Water	0.01	0.05	0.9
Log of CXI*	0.24	0.04	0.0001
Log of CXO*	0.06	0.02	0.02
Condition of residence†	0.77	0.11	0.0001
Refinish	-0.06	0.14	0.7

MODEL 2

Adj R^2 = 0.32; N = 433; Potential confounders and log soil			
Variable	**Parameter Estimate**	**Standard Error**	**P <**
Intercept	-5.44	0.55	0.0001
Log of Water	-0.004	0.04	0.9
Log of CXI*	0.20	0.04	0.0001
Log of CXO*	0.04	0.02	0.2
Condition of residence†	0.67	0.11	0.0001
Refinish	-0.03	0.13	0.9
Soil composition	0.53	0.09	0.0001

*Log of CXI, Log of CXO are the logarithms of the sum of indoor and outdoor lead paint measurements multiplied by ratings of the condition of the paint where each XRF reading was made.

†Condition of residence is the rating of the overall state of repair/disrepair of the house.

Table 13.—Geometric means of environmental testing from families with more than one child under 6 years of age and families with only one child under 6 years of age.

	Households with Two or More Children Under 6 Years of Age		Households with One Child Under 6 Years of Age	
Parameter	Mean Level of Parameter* BPb <10 μg/dl	BPb ≥10 μg/dl	Mean Level of Parameter* BPb <10 μg/dl	BPb ≥10 μg/dl
Distance to smelter†	5.3	4.5	5.4	4.7
CXRFI§	0.7	1.2	0.6	10.0
CXRFO¶	3.8	6.7	3.4	5.7
Indoor lead/paint**	0.8	1.1	0.7	10.0
Composite soil sample††	310	503	303	488
"Dust load"§§	200	700	150	600

*All environmental measurements are statistically significantly different at the $p < 0.05$ level between the high blood lead (≥ 0.48 μmol/L, ≥ 10 μg/dL) and the low blood lead groups for households with one child and households with more than one child.
†Distance to the smelter is an arithmetic mean.
§CXRFI is the average indoor XRF reading in mg/cm^2 multiplied by the condition code of the residence.
¶CXRFO is the average outdoor XRF reading in mg/cm^2 multiplied by the condition code of the residence.
**Indoor lead paint is the average indoor XRF lead paint reading in mg/cm^2.
††EPA soil sample is the lead concentration in ppm (mg/kg) of a composite soil sample taken from different areas of the yard, including play areas.
§§"Dust load" is the amount of dust (in μg) collected from a m^2 of area in the residence.

FIGURES

Figure 1.—Map of the study area showing the distribution of the residents. The closed circles represent residents with children with blood lead levels < 0.48 μmol/L (< 10 μg/dl). The open squares represent houses with children with blood lead levels of ≥ 0.48 μmol/L (≥ 10 μg/dl).

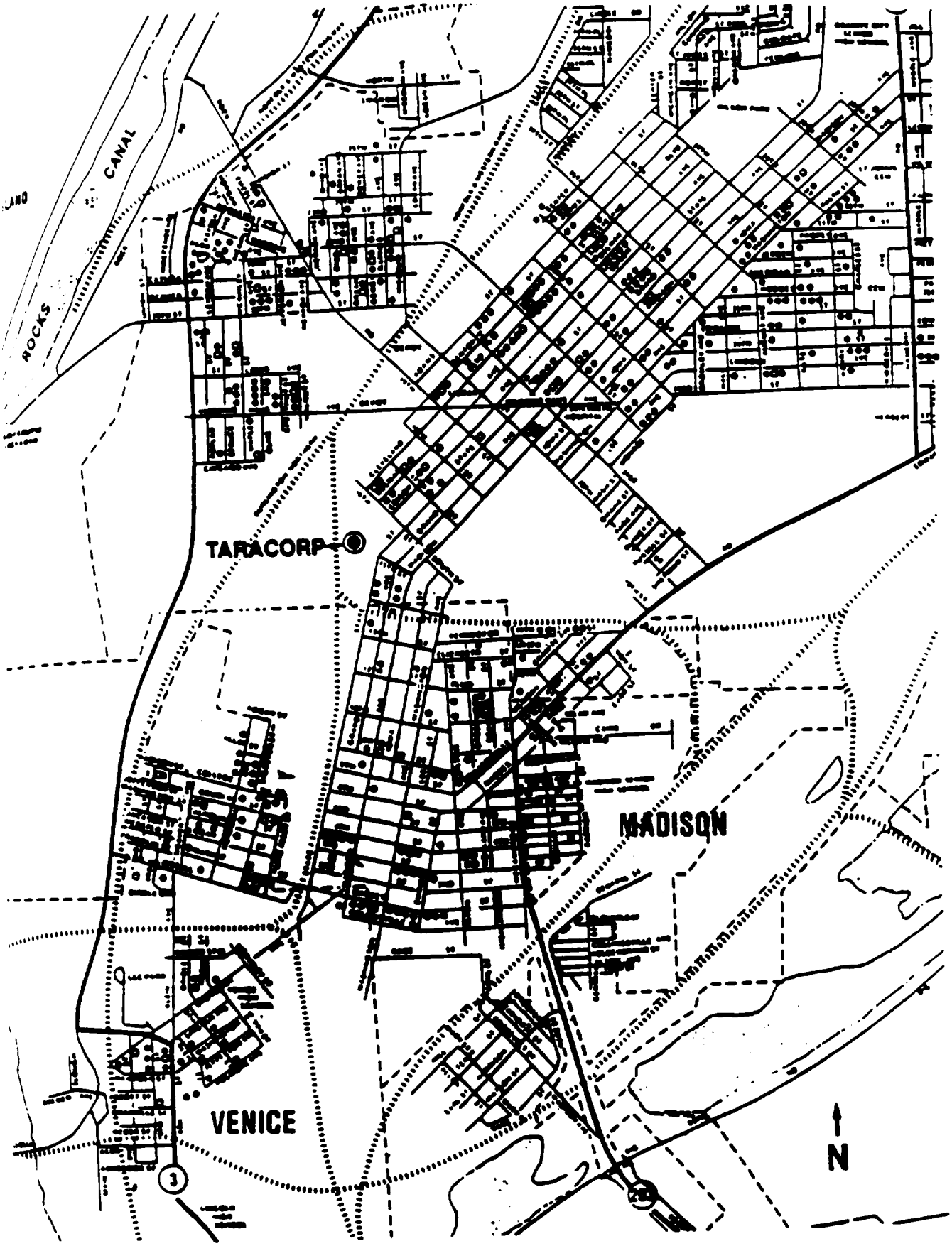

CANAL
ROCKS
TARACORP
MADISON
VENICE
N

Figure 2a.—Mean blood lead levels by age group for children with blood lead levels ≤ 0.48 μmol/L (≤ 10 μg/dl).

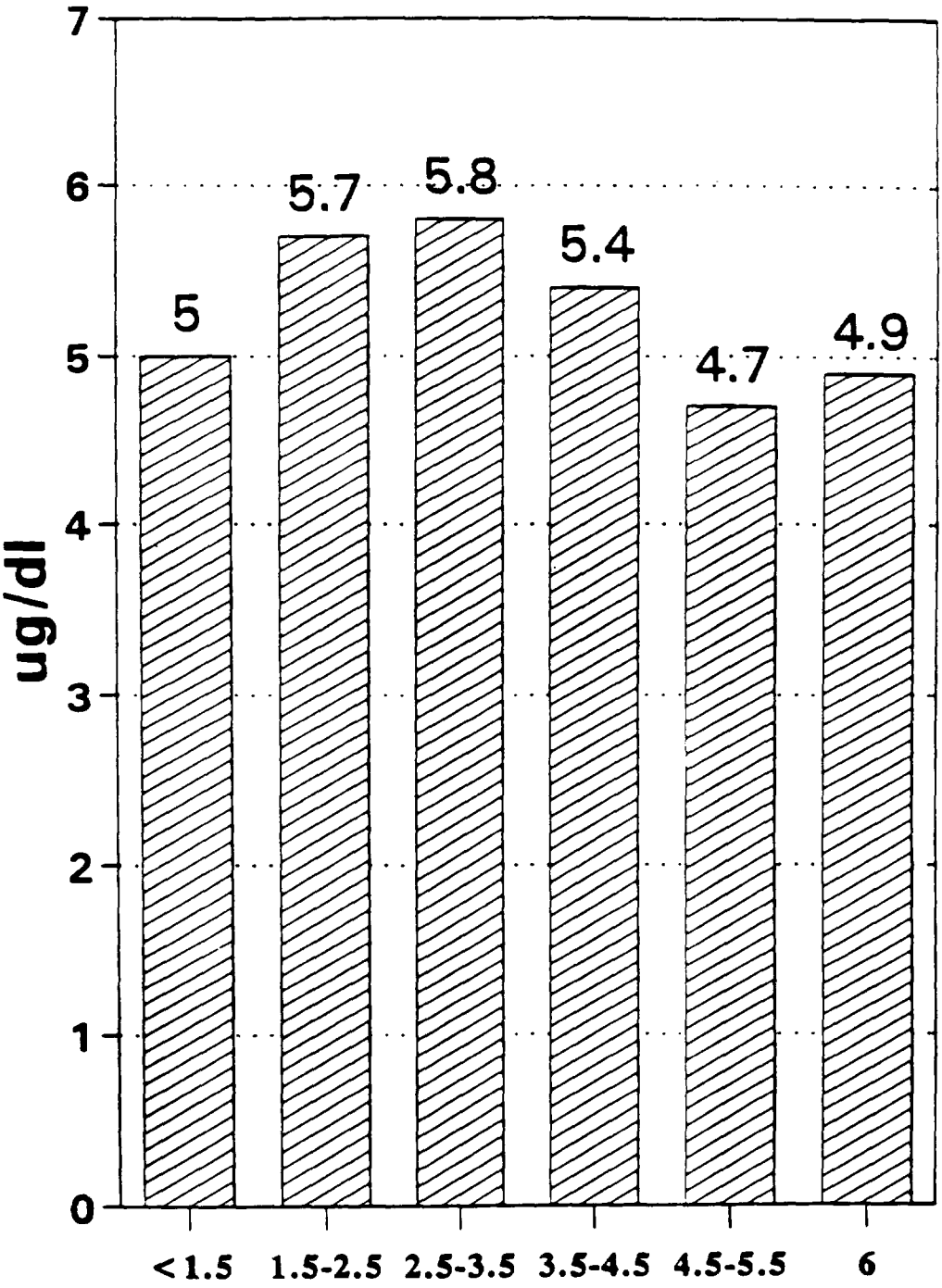

7
6
5
4
3
2
1
0
ug/dl
5
5.7
5.8
5.4
4.7
4.9
< 1.5
1.5-2.5
2.5-3.5
3.5-4.5
4.5-5.5
6
Age of Children in Years

Figure 2b.—Mean blood lead levels by age group for children with blood lead levels ≥ 0.48 μmol/L (≥ 10 μg/dl).

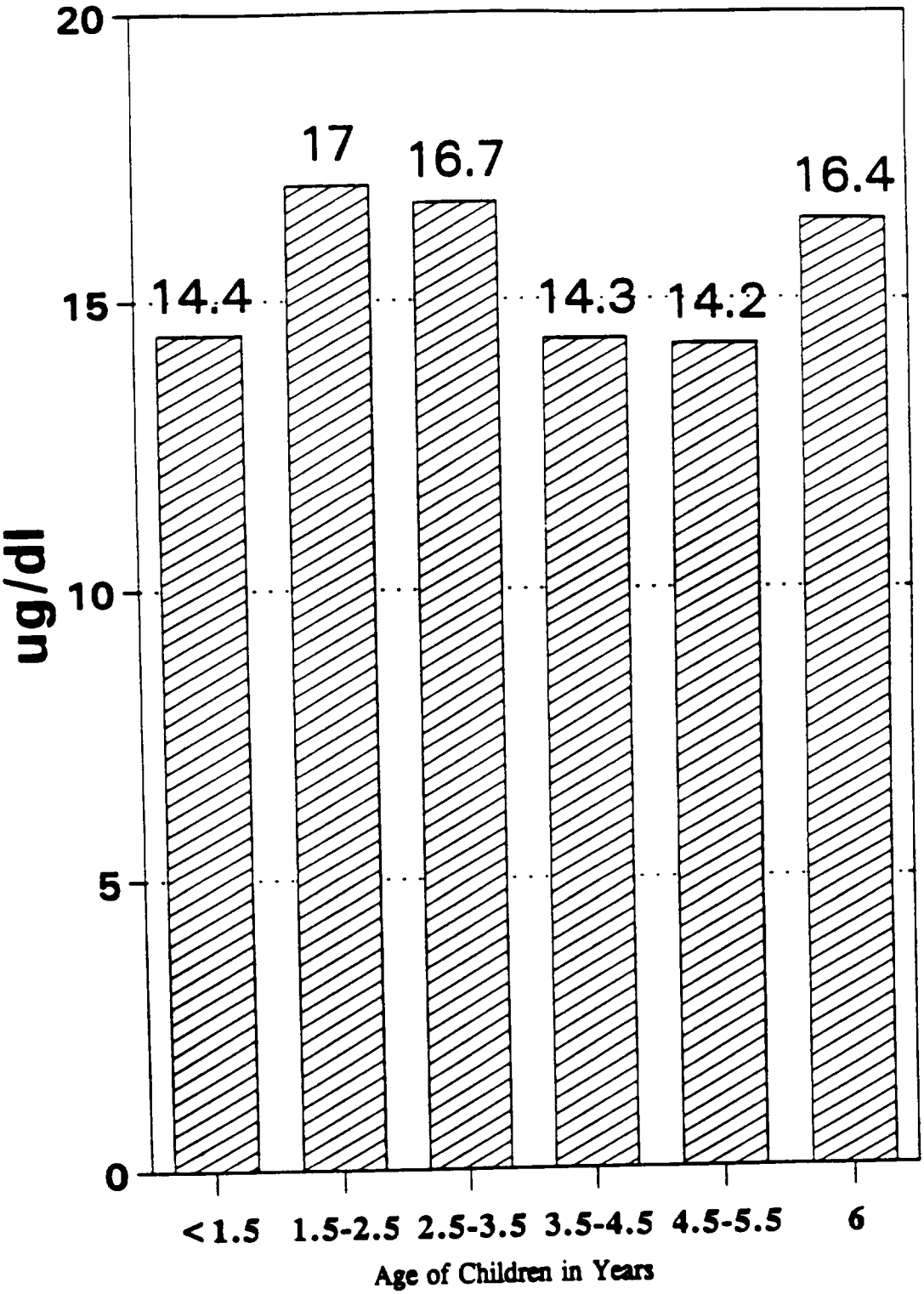
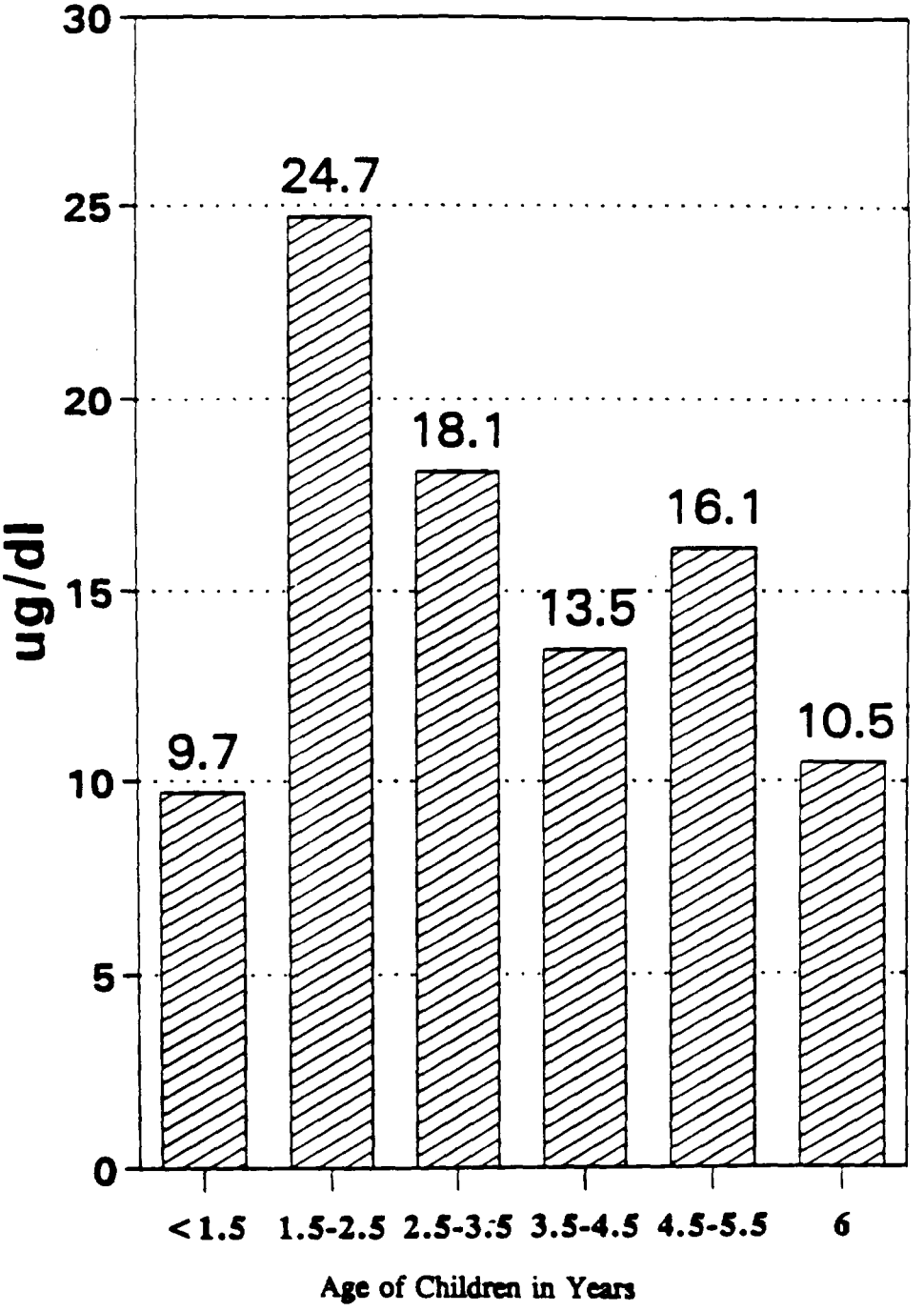

20
15
10
5
0
ug/dl
14.4
17
16.7
14.3
14.2
16.4
<1.5
1.5-2.5
2.5-3.5
3.5-4.5
4.5-5.5
6
Age of Children in Years

Figure 2c. Percent of children in each age group with blood lead levels ≥ 0.48 μmol/L (≥ 10 μg/dl).


30
25
20
15
10
5
0
ug/dl
24.7
18.1
16.1
13.5
10.5
9.7
<1.5
1.5-2.5
2.5-3.5
3.5-4.5
4.5-5.5
6
Age of Children in Years

APPENDICES

The contents of Appendices A through I are presented in their entirety as submitted by the authors and have not been revised to conform with the Agency for Toxic Substances and Disease Registry editorial guidelines.

Appendix A—Census Form

Illinois Department of Public Health
Madison County Lead Study
Census Form
Summer 1991

Census Block # _____
Census Taker ID _____
Census Household # _____

House Address _____

City _____ Zip _____ Phone _____

Check here if refused to answer all questions _____

List on the numbered lines below the names of each person living in this house or apartment. Begin with the head of the household and include all persons staying here who have no other home.

INCLUDE	DO NOT INCLUDE
Everyone who usually lives here such as family members, housemates and roommates, foster children, roomers, boarders, and live-in workers.	Persons who usually live somewhere else.
Persons who are temporarily away on a business trip, on vacation, or in a general hospital.	Persons who are institutionalized.
College students who stay here while attending college.	College students who live somewhere else while attending college.
Persons in the Armed Forces who live here.	Persons in the Armed Forces who live somewhere else.
Newborn babies still in the hospital.	
Children in boarding schools below the college level.	
Persons who stay here most of the week while working even if they have a home somewhere else.	Persons who stay somewhere else most of the week while working.

	Last	First	Initial
Person 1 (head):			
Person 2:			
Person 3:			
Person 4:			
Person 5:			
Person 6:			
Person 7:			
Person 8:			
Person 9:			
Person 10:			
Person 11:			
Person 12:			

Illinois Department of Public Health
Madison County Lead Study

Census Form

Summer 1991

Census Block # _____

Census Taker ID _____

Census Household #_____

CIRCLE THE BEST ANSWER AND WRITE NUMBER IN LOWER RIGHT HAND CORNER OF BOX

#1

Which describes this building best?

1. Mobile home or trailer
2. One family house detached from any other house
3. Duplex
4. Row house
5. Building with 2 apartments or less
6. Building with 3 or 4 apartments
7. Building with 5 to 9 apartments
8. Building with 10 or more apartments
9. Don't know

#2

How many rooms are in this house or apartment, excluding bathrooms or halls?

1. 2 or less
2. 3 to 4 rooms
3. 5 to 6 rooms
4. 7 to 8 rooms
5. 9 to 10 rooms
6. 11 or more rooms
7. Refused response
9. Don't know

#3

What year was this house or apartment built?

1. Before 1879
2. 1880 to 1899
3. 1900 to 1919
4. 1920 to 1939
5. 1940 to 1959
6. 1960 to 1979
7. 1980 to present
8. Refused response
9. Don't know

#4

Is this house or apartment

1. Owned by you or someone in this household with mortgage or loan?
2. Owned by you or someone in this household free and clear (without a mortgage)?
3. Rented for cash rent?
4. Occupied without payment of cash rent?
5. Other _____
6. Refused response
9. Don't know

#5

Which of the following best describes the highest level of education completed by the head of this household?

1. Grade school
2. Some high school
3. High school
4. Some college
5. College (BA, BS, RN, LPN, etc.)
6. Some postgraduate work
7. Postgraduate work (Master's, Ph.D. J.D., M.D., etc.)
8. Refused response
9. Don't know

#6

How long have you and your family occupied this apartment or house?

1. Less than 2 months
2. 3 months to 11 months
3. 1 year to 2 years
4. 3 years to 5 years
5. 6 years to 8 years
6. 9 years or more
7. Refused response
9. Don't know

#7

Is anyone in this residence pregnant?

1. Yes
   If yes, please give first name(s)
   _____
   _____
2. No
3. Refused response
9. Don't know

Illinois Department of Public Health
Madison County Lead Study

Form

Summer 1991

Census Block #_____

Census Taker ID_____

Census Household # _____

CIRCLE THE BEST ANSWER AND WRITE NUMBER IN LOWER RIGHT HAND CORNER OF BOX

Fill one column for each person listed on second page	Person # 1 Name	Person # 2 Name	Person # 3 Name	Person # 4 Name
#8 Is person 2 and others related to person 1? 1. Yes (go to #9A) 2. No (go to #9B)		1 2	1 2	1 2
#9 A. How are they related? 1. Husband/wife 2. Natural-born/adopted/ son/daughter 3. Step or foster child 4. Father/mother 5. Grandchild 6. Other 7. Refused response 9. Don't know		1 2 3 4 5 6 7 9	1 2 3 4 5 6 7 9	1 2 3 4 5 6 7 9
B. If not related: 1. Roomer, boarder 2. Housemate, roommate 3. Unmarried partner 4. Other non-relative 5. Refused response 9. Don't know		1 2 3 4 5 9	1 2 3 4 5 9	1 2 3 4 5 9
#10 Describe race of persons in your household. 1. Caucasian 2. African-American 3. Indian American 4. Eskimo or Aleut 5. Asian/Pacific Islander 6. Other 7. Refused response 9. Don't know	1 2 3 4 5 6 7 9	1 2 3 4 5 6 7 9	1 2 3 4 5 6 7 9	1 2 3 4 5 6 7 9
11 Sex	1. M 2. F	1. M 2. F	1. M 2. F	1. M 2.F
12 Age in Years				
13 Date of Birth (MM/DD/YY)	__/__/__	__/__/__	__/__/__	__/__/__
14 Marital Status 1. Now married 2. Widowed 3. Divorced 4. Separated 5. Single 6. Refused response 7. Don't know	1 2 3 4 5 6 9	1 2 3 4 5 6 9	1 2 3 4 5 6 9	1 2 3 4 5 6 9

Illinois Department of Public Health
Madison County Lead Study

Census Block #_____

Census Form

Census Taker ID_____

Summer 1991

Census Household # ___

CIRCLE THE BEST ANSWER AND WRITE NUMBER IN LOWER RIGHT HAND CORNER OF BOX

Fill one column for each person listed on second page	Person # 5 Name	Person # 6 Name	Person # 7 Name	Person # 8 Name
#8 Is person 2 and others related to person 1? 1. Yes (go to #9A) 2. No (go to #9B)	1 2	1 2	1 2	1 2
#9 A. How are they related? 1. Husband/wife 2. Natural-born/adopted/ son/daughter 3. Step or foster child 4. Father/mother 5. Grandchild 6. Other 7. Refused response 9. Don't know	1 2 3 4 5 6 7 9	1 2 3 4 5 6 7 9	1 2 3 4 5 6 7 9	1 2 3 4 5 6 7 9
B. If not related: 1. Roomer, boarder 2. Housemate, roommate 3. Unmarried partner 4. Other non-relative 5. Refused response 9. Don't know	1 2 3 4 5 9	1 2 3 4 5 9	1 2 3 4 5 9	1 2 3 4 5 9
#10 Describe race of persons in your household. 1. Caucasian 2. African-American 3. Indian American 4. Eskimo or Aleut 5. Asian/Pacific Islander 6. Other 7. Refused response 9. Don't know	1 2 3 4 5 6 7 9	1 2 3 4 5 6 7 9	1 2 3 4 5 6 7 9	1 2 3 4 5 6 7 9
#11 Sex	1. M 2. F	1. M 2. F	1. M 2. F	1. M 2.F
#12 Age in Years				
#13 Date of Birth (MM/DD/YY)	__/__/__	__/__/__	__/__/__	__/__/__
#14 Marital Status 1. Now married 2. Widowed 3. Divorced 4. Separated 5. Single 6. Refused response 9. Don't know	1 2 3 4 5 6 9	1 2 3 4 5 6 9	1 2 3 4 5 6 9	1 2 3 4 5 6 9

Illinois Department of Public Health
Madison County Lead Study

Census Block #_____

Form

Census Taker ID_____

Summer 1991

Census Household # _____

CIRCLE THE BEST ANSWER AND WRITE NUMBER IN LOWER RIGHT HAND CORNER OF BOX

Fill one column for each person listed on second page	Person # 9 Name _____	Person # 10 Name _____	Person # 11 Name _____	Person # 12 Name _____
#8 Is person 2 and others related to person 1?				
1. Yes (go to #9A)	1	1	1	1
2. No (go to #9B)	2	2	2	2
#9 A. How are they related?				
1. Husband/wife	1	1	1	1
2. Natural-born/adopted/ son/daughter	2	2	2	2
3. Step or foster child	3	3	3	3
4. Father/mother	4	4	4	4
5. Grandchild	5	5	5	5
6. Other	6	6	6	6
7. Refused response	7	7	7	7
9. Don't know	9	9	9	9
B. If not related:				
1. Roomer, boarder	1	1	1	1
2. Housemate, roommate	2	2	2	2
3. Unmarried partner	3	3	3	3
4. Other non-relative	4	4	4	4
5. Refused response	5	5	5	5
9. Don't know	9	9	9	9
#10 Describe race of persons in your household.				
1. Caucasian	1	1	1	1
2. African-American	2	2	2	2
3. Indian American	3	3	3	3
4. Eskimo or Aleut	4	4	4	4
5. Asian/Pacific Islander	5	5	5	5
6. Other	6	6	6	6
7. Refused response	7	7	7	7
9. Don't know	9	9	9	9
#11 Sex	1. M 2. F	1. M 2. F	1. M 2. F	1. M 2.F
#12 Age in Years				
#13 Date of Birth (MM/DD/YY)	__/__/__	__/__/__	__/__/__	__/__/__
#14 Marital Status				
1. Now married	1	1	1	1
Widowed	2	2	2	2
Divorced	3	3	3	3
4. Separated	4	4	4	4
5. Single	5	5	5	5
6. Refused response	6	6	6	6
9. Don't know	9	9	9	9

Illinois Department of Public Health
Madison County Lead Study

Census Block #_____

Census Form

Census Taker ID_____

Summer 1991

Census Household #_____

ANIMAL DATA - CIRCLE THE ANSWER THAT BEST APPLIES

1. Do you keep a cat or dog at your dwelling?

   1. Yes (if yes go to next question)
   2. No

2. If yes, what is the species, sex, age, and how long had you had each individual animal?

Animal #	1	2	3	4	5	6
Name						
Species 1. Dog 2. Cat	 1 2	 1 2	 1 2	 1 2	 1 2	 1 2
Sex 1. Male 2. Female 3. Neutered	 1 2 3	 1 2 3	 1 2 3	 1 2 3	 1 2 3	 1 2 3
Age in months or DK*	___ DK	___ DK	___ DK	___ DK	___ DK	___ DK
Months of Possession or DK*	___ DK	___ DK	___ DK	___ DK	___ DK	___ DK

*DK-don't know

Years	Months	Years	Months	Years	Months
0.5	6	5.5	66	10.5	126
1.0	12	6.0	72	11.0	132
1.5	18	6.5	78	11.5	138
2.0	24	7.0	84	12.0	144
2.5	30	7.5	90	12.5	150
3.0	36	8.0	96	13.0	156
3.5	42	8.5	102	13.5	162
4.0	48	9.0	108	14.0	168
4.5	54	9.5	114	14.5	174
5.0	60	10.0	120	15.0	180

Illinois Department of Public Health

Madison County Lead Study Census Block # _____

Summer 1991

The Illinois Department of Public Health thanks you for your cooperation. The census information given to the Illinois Department of Public Health will be used to help determine which particular areas to study. We need some of this information to choose groups of residents that may be exposed to lead as well as similar groups of residents that are not exposed.

You should have received a copy of the consent form that will be used for this study. We are distributing this now so that you have plenty of time to read it in advance if you are asked to participate.

If you did not receive a copy of the consent form or if you have any further questions regarding this study, please contact:

Tom Long
Illinois Department of Public Health
Division of Environmental Health
525 West Jefferson Street
Springfield, Illinois 62761
(217) 782-5830

David Webb
Illinois Department of Public Health
22 Kettle River Drive
Edwardsville, IL 62025
(618) 656-6680

Cathy Copley, Illinois Department of Public Health
2125 S. First Street
Champaign, IL 61820
(217) 333-6914

* LEAVE THIS PAGE AT HOUSEHOLD AFTER CENSUS COMPLETED *

Printed by Authority of the State of Illinois
P.O. 53010 7M 7/91

Appendix B—Consent Form

PROTECTION OF HUMAN SUBJECTS
ASSURANCE/CERTIFICATION/DECLARATION

☒ ORIGINAL ☐ FOLLOWUP ☐ EXEMPTION (previously undesignated)

continuation continuation

APPLICATION IDENTIFICATION NO. *(if known)*

: *A research activity involving human subjects that is not exempt from HHS regulations may not be funded unless an institu-* *onal Review Board (IRB) has reviewed and approved the activity in accordance with Section 474 of the Public Health Service Act as* *plemented by Title 45, Part 46 of the Code of Federal Regulations (45 CFR 46—as revised). The applicant institution must submit* *rtification of IRB approval to HHS unless the applicant institution has designated a specific exemption under Section 46.101(b) which* *plies to the proposed research activity. Institutions with an assurance of compliance on file with HHS which covers the proposed* *tivity should submit certification of IRB review and approval with each application. (In exceptional cases, certification may be* *cepted up to 60 days after the receipt date for which the application is submitted.) In the case of institutions which do not have an* *surance of compliance on file with HHS covering the proposed activity, certification of IRB review and approval must be submitted* *thin 30 days of the receipt of a written request from HHS for certification.*

TITLE OF APPLICATION OR ACTIVITY

Multiagency heavy metals exposure study in Illinois, Kansas, and Missouri (Summer '91)

PRINCIPAL INVESTIGATOR, PROGRAM DIRECTOR, OR FELLOW

Thomas F. Long

FOOD AND DRUG ADMINISTRATION REQUIRED INFORMATION *(see reverse side)*

HHS ASSURANCE STATUS

☐ This institution has an approved assurance of compliance on file with HHS which covers this activity.

M1311 Assurance identification number 01 IRB identification number

☒ No assurance of compliance which applies to this activity has been established with HHS, but the applicant institution will provice written assurance of compliance and certification of IRB review and approval in accordance with 45 CFR 46 upon request.

CERTIFICATION OF IRB REVIEW OR DECLARATION OF EXEMPTION

ctivity has been reviewed and approved by an IRB in accordance with the requirements of 45 CFR 46, including its relevant Subparts. This certifi- *un fulfills, when applicable, requirements for certifying FDA status for each investigational new drug or device. (See reverse side of this form.)*

6/20/91 Date of IRB review and approval. *(If approval is pending, write "pending." Followup certification is required.)*
(month/day/year)

☒ Full Board Review ☐ Expedited Review

☐ This activity contains multiple projects, some of which have not been reviewed. The IRB has granted approval on condition that all projects covered by 45 CFR 46 will be reviewed and approved before they are initiated and that appropriate further certification *(Form HHS 596)* will be submitted.

Human subjects are involved, but this activity qualifies for exemption under 46.101(b) in accordance with paragraph _____ *(insert paragraph number of exemption in 46.101(b), 1 through 5)*, but the institution did not designate that exemption on the application.

. Each official signing below certifies that the information provided on this form is correct and that each institution assumes responsibility for assuring required future reviews, approvals, and submissions of certification.

APPLICANT INSTITUTION	COOPERATING INSTITUTION
AME, ADDRESS, AND TELEPHONE NO. oard of Trustees of outhern Illinois University arbondale, Il 62901 17/782-3318	NAME, ADDRESS, AND TELEPHONE NO. Illinois Department of Public Health 525 West Jefferson Springfield, Il 62761 217/782-5830
AME AND TITLE OF OFFICIAL *(print or type)* ichard C. Moy, Dean and Provost, for . C. Guyon, Ph.D., President, SIU	NAME AND TITLE OF OFFICIAL *(print or type)* John R. Lumpkin, M.D., Director 6/25/91
GNATURE OF OFFICIAL LISTED ABOVE *(and date)* Richard H. Moy 6/26/91	SIGNATURE OF OFFICIAL LISTED ABOVE *(and date)* John R. Lumpkin 6/27/9

HS 596 (Rev. 1/82) *(If additional space is needed, please use reverse side under "Notes*

Southern Illinois University
School of Medicine
Springfield Committee
for Research Involving Human Subjects

Protocol #: 91-37
(to be assigned by Office of ADR)

Application for Approval of a Research Protocol

Instructions to Principal Investigators: Complete either A, B, or C as appropriate to your protocol. Please call the Office of the Associate Dean for Research, 782-7936, if you have questions.
Please Submit: One (1) copy of this application form along with the appropriate number of copies of other materials as indicated below to the Office of the Associate Dean for Research, 801 North Rutledge, Springfield, Illinois.

I. Investigator: Thomas E. Long

Department: Illinois Department of Public Health Telephone: (217) 782-5830

Co-Investigator(s): Catherine Copley

Title of Protocol: Multisite Heavy Metal Exposure Study in Illinois, Kansas and Missouri

Funding: ___Departmental ___CRC X External (Specify) Agency for Toxic Substances and Disease Registry

Approval of Department Chair Indicated by Signature: [signature] M.D., M.P.H.
Assistant Director for Health Protection, IDPH

Other Department Involved: ___Yes X No

If Yes, Approval of Department Chair Indicated by Signature: _____

This Protocol will be implemented at:

____ Memorial Medical Center

____ St. John's Hospital

__X__ Neither

A. **Research presenting risk to subjects:** e.g. drug and medical device trials, surgical and other invasive procedures, studies involving randomization, placebo controls, etc.

Please Submit:
1. Thirty (30) copies of the complete protocol;
2. Thirty (30) copies of a consent form prepared on Form SCRIHS-B 12/82.

B. **Research presenting minimal risk to subjects:** In order for your study to be categorized as a "MINIMAL RISK" project, it must fall into one or more of the following areas. Please indicate the category:

____ 1. Collection of hair and nail clippings in a nondisfiguring manner; deciduous teeth; and permanent teeth if patient care indicates a need for extraction.

financial standing or employability; and (iii) the research deals with sensitive aspects of the subject's own behavior, such as illegal conduct, drug use, sexual behavior, or use of alcohol.

____ 4. Research involving the observation (including observation by participants) of public behavior, except where all of the following conditions exist: (i) observations are recorded in such a manner that the human subjects can be identified, directly or through identifiers linked to the subjects; (ii) the observations recorded about the individual, if they became known outside the research, could reasonably place the subject at risk of criminal or civil liability or be damaging to the subject's financial standing or employability; and (iii) the research deals with sensitive aspects of the subject's own behavior such as illegal conduct, drug use, sexual behavior, or use of alcohol.

____ 5. Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

Please submit
1. Three (3) copies of the protocol.

II. All investigators must sign the following statement of assurance:

The proposed investigation involves the use of human subjects. I am submitting this form with a description of my protocol prepared in accordance with institutional policy for the protection of human subjects participating in research. I am responsible for:

- insuring that informed consent is documented by the use of a written consent form approved by the IRB and signed by the subject or the subject's legally authorized representative and that each person signing the form is given a copy;
- placing the consent documents signed by human research subjects in a repository approved by the Associate Dean for Research;
- reporting the progress of the research to the Associate Dean for Research as often as and in the manner prescribed by SCRIHS but no less than once per year;
- reporting promptly through my department head to the Associate Dean for Research any injuries to human subjects or any unanticipated problems which involve risks to the human research subjects or others;
- reporting promptly through my department head to the Associate Dean for Research proposed changes in my research activity. I understand that changes in research during the period for which SCRIHS approval has already been given, shall not be initiated by me without SCRIHS review and approval, except where necessary to eliminate apparent immediate hazards to the subject;
- reporting promptly to the Associate Dean for Research and SCRIHS any serious or continuing noncompliance with the requirements of the SCRIHS General Assurance or the determinations of SCRIHS.

Thomas F. Long — 4/26/91

Signature of Principal Investigator — Date

Note: Please refer to **Southern Illinois University School of Medicine, Springfield Committee for Research Involving Human Subjects Assurance of Compliance with HHS Regulations for Protection of Human Research Subjects** for policy regarding research involving human subjects.

INFORMED CONSENT FORM

Informed consent consists of the following elements:

-A fair explanation in terms the subject can understand, of the procedures to be followed and their purposes including an identification of those which are experimental and a statement of the expected duration of the subject's participation;

-A description of any reasonably foreseeable discomforts or risks:

-A description of any benefits reasonably to be expected;

-A disclosure of any appropriate alternative procedures that might be advantageous for the subject;

-A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. If the protocol is a FDA study, a statement should be added to the standard paragraph on confidentiality that the subject understands his or her identity will be revealed to the FDA;

-An explanation of compensation for injuries incurred in research;

-A offer to answer any inquiries concerning procedures;

-An instruction that the subject is free to withdraw his/her consent and to discontinue participation in the project or activity at any time without prejudice to the subject;

-No language through which the subject is made to waive or to appear to waive any of his/her legal rights or to release the institution or its agents from liability or negligence.

The following additional elements may be required depending on the nature of the protocol:

-A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or may become pregnant) which are currently unforeseeable;

-Anticipated circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's consent;

-Any additional costs to the subject that may result from participation in the research;

-The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

-A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and

The approximate number of subjects involved in the study.

Individuals responsible for this research protocol:

Fred Stallings
Sara Sarasuwa
Agency for Toxic Substances and Disease Registry
Executive Park
Atlanta, Georgia
(404) 639-0564

Thomas Long
Catherine Copley
Illinois Department of Public Health
Division of Environmental Health
525 West Jefferson
Springfield, IL 62761
(217) 782-5830

Title of protocol: Multisite Heavy Metal Exposure Study in Illinois, Kansas, and Missouri

Expected duration of patient involvement in study: It may take approximately a total of two hours to review this consent form, answer questions about activities in and around the home, take my (child's/ward's) blood pressure, collect the urine sample, and draw the blood sample. It may take approximately three hours for researchers to do the necessary environmental work which may include collection of soil, water, and dust samples as well as a paint survey of the home.

I (My child/ward) agree(s) to participate as a subject in this research project, the main purpose of which is: To determine levels of heavy metals in blood and urine in people living in the study area to compare to those levels found in people living outside the study area as well as to currently accepted health guidelines; to determine any relationship between heavy metal levels found in blood and urine and those levels in environmental samples (soil, dust, paint, and water); to determine if those circumstances which may present greater risks of exposure to heavy

metals; and to determine if measurements of some blood components can be identified that may indicate heavy metal exposures.

Description of research protocol (to include objectives, purposes, selection of patients, procedures to be followed, treatment plan, etc.): The Illinois Department of Public Health (IDPH) with assistance for the Agency for Toxic Substances and Disease Registry of the U.S. Public Health Service, is conducting an exposure study of heavy metal contamination in residential areas surrounding the N L Industries/Taracorp National Priority List (NPL) site in Granite City, Illinois. The goals of the study are as follows:

1. To compare my (child'/ward's) heavy metal levels in blood and urine to those found in people living in other areas.

2. To compare the amount of heavy metals in my environment with those found in other areas.

3. To analyze some of my blood components and see how they compare with those found in people living in other areas.

4. To compare the results of the tests of blood mentioned above with the standard reference ranges for these tests.

5. To determine if there is a statistical relationship between activities and/or situations in and around the home and the amount of heavy metals found in my (child's/ward's) body.

6. To compare the levels of heavy metals found in my (child's/ward/s) blood and the levels of blood components.

7. To compare the results of my community's exposure with people living in areas contaminated by both industrial and mining emissions.

As a resident, I am being asked to participate in order to determine the degree of my (child's/ward's) exposure to heavy metals. This study will include some people living within two miles of the NPL site. The individuals doing this study would like to include all children between the ages of 6 months through 71 months. Some older children and adults, chosen randomly, like tossing a coin, will be asked to participate. My (child's/ward's) part in the study may include:

1. Answering questions about habits and activities in and around the home and about the occupations of adults in the home. Questions concerning financial status will be asked as well. This interview will require about one hour.

2. Having blood pressure measured.

3. Permitting a blood sample not to exceed 30 milliliters (about 2 tablespoons) to be taken with a sterile needle from a vein in the arm. I (My child/ward) may be asked to provide a second sample at a future date to measure changes over time.

4. Providing a urine sample by voiding into a container. A container and instructions will be given to me. The sample may be picked up later. No urine is to be collected from infants.

5. Allowing testing on blood and urine samples for heavy metals and associated biological measurements. Some of the blood work for immunological tests is considered experimental.

6. Allowing environmental samples to be collected from in and around the home. This will require IDPH or their representatives to enter the home and conduct a survey of paint. In addition, water, dust, and soil samples may be collected to be analyzed for heavy metals. The sample collection may require up to three hours.

I understand that of the procedures described above, the following are experimental procedures: None.

I understand that the reasonable foreseeable risks or discomforts may be as follows: There is little risk associated with the blood drawing procedure. The needle will be left in my (child's/ward's) arm for a few minutes. I (My child/ward) can expect to experience some pain at the moment the needle goes into the arm. In about 10 percent of cases, a small amount of bleeding under the skin will produce a bruise (hematoma). There is a very small risk of temporary clotting of the vein, infection, or fainting.

I understand that the benefits which may reasonably be expected from my (my child's ward's) participation in this study are: I will know what kind of environment I live in and if I have been exposed to lead. A copy of this consent form will be given to me. Results of blood, urine, and immediate environment tests will be provided to me and/or our physician at no charge. I will be provided with recommendations to reduce the amount of exposure to heavy metals if results reflect potential of excessive heavy metal exposure. We will be included on a mailing list and will receive a copy of the final report.

I am aware that the following alternative procedures could be advantageous to me: Getting the same tests done by a private company or laboratory. I could choose to do nothing.

Discussion of additional elements of informed consent, if applicable. If none are applicable, please state.

Confidentiality is assured since IDPH will take every reasonable precaution to keep my (my child's/ward's) records confidential. Any information shared with the Agency for Toxic Substances and Disease Registry or Centers for Disease Control will be kept in accordance with the Federal Privacy Act of 1974 and will not include information which identifies me (my child/ward) personally. Any reports of this study will not identify specific individuals and will only give group information.

We understand that we may be asked to participate in future studies to measure heavy metal blood levels and environmental contamination concentration changes over time.

This protocol has been reviewed and approved by the Springfield Committee for Research Involving Human Subjects as preserving safeguards of subjects' privacy, welfare, and civil liberties. The Chairman of the Committee may be reached through the Office of the Dean and Provost, Southern Illinois University School of medicine, 801 North Rutledge Street, Springfield, Illinois 62708, telephone (217) 782-3318

I may contact the following person to answer any inquiries I may have concerning this research protocol and my rights as a resear subject: Catherine Copley; Illinois Department of Public Healt 525 West Jefferson; Springfield, IL 62761; (217) 782-5830 or David Webb; Illinois Department of Public Health; 22 Kettle River Drive; Edwardsville, IL 62025; (618) 656-6680.

I understand that my (child's/ward's) participation in this study is entirely voluntary and that I may decline to enter this study or withdraw from it any time. If I wish to withdraw, I understand that it is important to notify my doctor so that he or she can plan for my continuing medical care.

Any information obtained from this investigation which can be identified with me will remain confidential or will be disclosed only with my permission. Should any publication or public presentation result from this study, my (child's/ward's) identity will not be revealed.

I understand, in the event of any research-related injury resulting from research procedures, that financial compensation is not available, but that immediate medical treatment for injuries is available at usual and customary fees at St. Elizabeth's Medical Center in Granite City, Illinois. I also understand that should I (my child/ward) suffer any physical injury as a result of participation in the research program, I may contact the Chairman Springfield Committee for Research Involving Human Subjects,

Southern Illinois University School of Medicine, 801 North Rutledge Street, Springfield, Illinois, 62708, telephone number (217) 782-3318, who will review the matter with me and identify any other resources that may be available to me.

Printed Name of Participant: _____

Signatures:

_____
Subject, Legal Guardian, or Next of Kin — Date

_____
Participant under 18 Years of Age — Date

_____
Principal Investigator — Date

_____
Witness — Date

(Date consent form approved by SCRIHS: 6/20/91)

SCRIHS
6-20-91
Date

INFORMED CONSENT FORM

Informed consent consists of the following elements:

-A fair explanation in terms the subject can understand, of the procedures to be followed and their purpose including an identification of those which are experimental and a statement of the expected duration of the subject's participation;

-A description of any reasonably foreseeable discomforts or risks;

-A description of any benefits reasonably to be expected;

-A disclosure of any appropriate alternative procedures that might be advantageous for the subject;

-A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. If the protocol is a FDA study, a statement should be added to the standard paragraph on confidentiality that the subject understands his or her identity will be revealed to the FDA;

-An explanation of compensation for injuries incurred in research;

-An offer to answer any inquiries concerning procedures;

-An instruction that the subject is free to withdraw his/her consent and to discontinue participation in the project or activity at any time without prejudice to the subject;

-No language through which the subject is made to waive or to appear to waive any of his/her legal r to release the institution or its agents from liability or negligence.

The following additional elements may be required depending on the nature of the protocol:

-A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo fetus, if the subject is or may become pregnant) which are currently unforeseeable;

-Anticipated circumstances under which the subject's participation may be terminated by the research investigator without regard to the subject's consent;

-The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject;

-A statement that significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation will be provided to the subject; and;

-The approximate number of subjects involved in the study.

Individuals responsible for this research protocol;

Fred Stallings
Sara Sarasuwa
Agency for Toxic Substances and Disease Registry
Executive Park
Atlanta, Georgia
(404) 639-0564

Thomas Long
Catherine Copley
Illinois Department of Public Health
Division of Environmental Health
525 West Jefferson
Springfield, IL 62761
(217) 782-5830

Title of protocol: Multisite Heavy Metals Exposure Study in Illinois, Kansas, and Missouri

ected duration of patient involvement in study: It will take approximately 1 and 1/2 hours to review this consent form, complete the questionnaire, collect the urine sample, and collect the biological samples. It will take at least 1 hour to collect soil, water, paint, and dust samples from my home.

I (My child/ward) agree(s) to participate as a subject in this research project, the main purpose of which is: To determine levels of heavy metals in blood and urine in people living in the study area to compare to those levels found in people living outside the study area as well as to currently accepted health guidelines; to determine any relationship between heavy metal levels found in blood and urine and levels in soil, dust, paint, and water; to determine risk factors for exposure to lead and cadmium.

Description of research protocol (to include objectives, purposes, selection of patients, procedures to be followed, treatment plan, etc.): The Illinois Department of Public Health (IDPH) with assistance from the Agency for Toxic Substances and Disease Registry of the U.S. Public Health service, is conducting an exposure study of heavy metal contamination in residential areas surrounding the N L Industries/Taracorp National Priority List (NPL) site in Granite City, Illinois. I am being asked to participate in this study:

1. To determine if there is a statistical relationship between activities and/or situations in and around the home and the amount of heavy metals found in my (child's/ward's) body.

2. To compare the levels of heavy metals found in my (child's/ward's) blood to the levels of blood components.

3. To compare the results of my community's exposure with people living in areas contaminated to both industrial and mining emissions.

a resident, I am being asked to participate in order to determine the degree of my (child's/ward's) exposure to avy metals. This study will include some people living within two miles of the NPL site. The individuals doing this study would like to include all children between the ages of 6 months through 71 months. Some older children and adults, chosen randomly, like tossing a coin, will be asked to participate. My (child's/ward's) part in the study may include:

1. Answering questions about habits and activities in and around the home and about the occupations of adults in the home. This interview will require about one hour.

2. Permitting a blood sample not to exceed 30 milliliters (about 2 tablespoons) to be taken with a sterile needle from a vein in the arm.

3. Providing a urine sample by voiding into a cup in the privacy of an enclosed area. Instructions will be given to help my (my child/ward) use the cup to collect urine. Parents will be asked to help small children.

4. Allowing environmental samples to be collected from in and around the home at a later date. This will require IDPH or their representatives to enter my home and conduct a test of exterior and interior paint which will cause minimal damage to paint. In addition, water, dust, and soil samples will be collected to be analyzed for lead and cadmium.

I understand that of the procedures described above, the following are experimental procedures: None.

I understand that the reasonable foreseeable risks or discomforts may be as follows: There is little risk associated with the blood drawing procedure. The needle will be left in my (child's/ward's) arm for a few minutes. I (My child/ward) can expect to experience some pain at the moment the needle goes into the arm. In about 10 percent of cases, a small amount of bleeding under the skin will produce a bruise (hematoma). There is a small risk of fainting.

I understand that the benefits which may reasonably be expected from my (my child's/ward's) participation in this study are: In 6 to 8 months IDPH will send me a letter with my (my child's/ward's) test results and results of the environmental sampling, at no charge. If the results of medical tests indicate a possible problem, I will be notified as

soon as possible. Otherwise, IDPH will notify me of the results as soon as all tests are done. If further medical evaluation is indicated, recommendations will be given to seek further medical advice. Test results will be sent family physician if I request it in writing. Recommendations to reduce the amount of exposure to lead and/or cadmium will be provided if results reflect excessive lead or cadmium exposure.

I am aware that the following alternative procedures could be advantageous to me: Getting the same tests done private company or laboratory. I could choose to do nothing.

Discussion of additional elements or informed consent, if applicable. If none are applicable, please state.

IDPH will take every reasonable precaution to keep my (my child's/ward's) records confidential.

This protocol has been reviewed and approved by the Springfield Committee for Research Involving Human Sub as preserving safeguards of subjects' privacy, welfare, and civil liberties. The Chairman of the Committee may b reached through the Office of the Dean and Provost, Southern Illinois University School of Medicine, 801 North Rutledge Street, Springfield, Illinois 62708, telephone (217) 782-3318.

I may contact the following person to answer any inquiries I may have concerning this research protocol and my rights as a research subject: Catherine Copley; Illinois Department of Public Health; 525 West Jefferson; Spring IL 62761; (217) 782-5830 or David Webb; Illinois Department of Public Health; 22 Kettle River Drive; Edwardsv IL 62025; (618) 656-6680.

I understand that my (child's/ward's) participation in this study is entirely voluntary and that I may decline to e this study or withdraw from it any time.

Any information obtained from this investigation which can be identified with me will remain confidential or w disclosed only with my permission. Should any publication or public presentation result from this study, my (child's/ward's) identity will not be revealed.

I understand, in the event of any research-related injury resulting from research procedures, that financial compensation is not available, but that immediate medical treatment for injuries is available at usual and custor fees at St. Elizabeth's Medical Center in Granite City, IL. I also understand that should I (my child/ward) suffer physical injury as a result of participation in the research program, I may contact the Chairman, Springfield Committee for Research Involving Human Subjects, Southern Illinois University School of Medicine, 801 North Rutledge Street, Springfield, IL, 62708, telephone number (217) 782-3318, who will review the matter with me identify any other resources that may be available to me.

Printed Name of Participant: _____

Signatures:

_____

Subject, Legal Guardian, or Next of Kin

_____

Participant under 18 Years of Age

_____

Principal Investigator

_____

Witness

APPROVED BY
SCRIHS
6/20/91
Date

Amended 7/3/92

amended 4/92

Appendix C—Questionnaires

HEAVY METAL EXPOSURE ASSESSMENT QUESTIONNAIRE

PARTICIPANT ID NUMBER __ __ __ __ - __ __ __ __

HOUSE ID NUMBER __ __ __ __

Street Address:

Street _____ Apt._____

City _____ State_____

Zip code _____

Mailing Address:

Street _____ Apt._____

City _____ State_____

Zip code _____

Telephone number:

home (__ __ __) __ __ __ - __ __ __ __

work (__ __ __) __ __ __ - __ __ __ __

1 = Phone
2 = No phone
8 = REFUSED
9 = DON'T KNOW

(001-004) HOUSE ID ___ ___ ___ ___

(005-010) DATE __ __/__ __/__ __

100 HOUSEHOLD QUESTIONNAIRE

THE FOLLOWING QUESTIONS MUST BE ANSWERED BY PARENT OR LEGAL GUARDIAN IF THE SUBJECT IS AGED 14 OR YOUNGER.

First, I would like to ask you some questions about the home you/SUBJECT lives in (WHERE SUBJECT LIVES MOST OF THE TIME IN THE LAST 90 DAYS)

(Circle applicable answer.)

(011-012) 101. What year was this house built? (OLDEST PART)

00 = <1900-1909
01 = 1910-1919
02 = 1920-1929
03 = 1930-1939
04 = 1940-1949
05 = 1950-1959
06 = 1960-1969
07 = 1970-1979
08 = 1980-1989
09 = 1990-present
99 = DON'T KNOW

(013) 102. What type of exterior does your/SUBJECT'S home have?

1 = wood
2 = brick
3 = block
4 = mobile home
5 = vinyl/metal siding
6 = Other _____
9 = DON'T KNOW

(014) 103. Is the home you/SUBJECT live in rented or owned?

1 = rent
2 = own
3 = other _____
8 = REFUSED
9 = DON'T KNOW

(015) 104. What type of water pipes does the home contain?

1 = lead
2 = plastic
3 = galvanized steel
4 = copper
5 = iron
6 = mixed (specify) _____
7 = Other (specify) _____
9 = DON'T KNOW

HOUSE ID ___ ___ ___ ___

105. What type of water does your/SUBJECT'S household normally use most for:

	Drinking (016)	Cooking (017)
Private well water	1	1
Public water (city or district)	2	2
Bottled	3	3
Local spring or brook	4	4
Cistern	5	5
Other _____	6	6
DON'T KNOW	9	9

106. Which fuel do you use most for: (Circle one per column)

	House Heating (018)	Water Heating (019)	Cooking (020)
Gas--bottled or tank	1	1	1
Gas--pipes (natural gas)	2	2	2
Electricity	3	3	3
Fuel oil or kerosene	4	4	4
Coal or coke	5	5	5
Wood	6	6	6
Other _____	7	7	7
DON'T KNOW	9	9	9

107. Has any part of your house been repainted, sanded, or chemically or heat stripped, or otherwise refinished within the last year?

(021)
1 = Yes
2 = No
9 = DON'T KNOW

IF YES, Approximately when was this most recently done?

(022-025) ___ ___ / ___ ___
(MONTH / YEAR) (ENTER 99 IF DON'T KNOW MONTH)

108. Do you use air conditioning in your/SUBJECT'S home?

(026)
1 = Yes
2 = No
9 = DON'T KNOW

HOUSE ID __ __ __ __

HOUSEHOLD ACTIVITIES/OCCUPATIONS

Now I'd like to ask you some questions about the work and hobbies of all persons living in this home. (ALL household members included)

(027) 109. Have any members of the household worked in mining or a mining related job such as mine material handling or transportation in the last 90 days?

1 = Yes
2 = No (GO TO 114)
9 = DON'T KNOW (GO TO 114)

110. What type of mining or mine related work have household members done in the last 90 days? (Circle all that apply.)

			Yes	No	Don't know
(028)	a.	Underground	1	2	9
(029)	b.	Surface	1	2	9
(030)	c.	Milling	1	2	9
(031)	d.	Transportation/ handling	1	2	9
(031)	e.	Clerical/Admin.	1	2	9
(032)	f.	Smelter	1	2	9
(033)	g.	Other	1	2	9

IF OTHER, SPECIFY: _____

111. What type of mine or mine materials have household members worked with in the last 90 days? (Circle all that apply.)

			Yes	No	Don't know
(034)	a.	Lead	1	2	9
(035)	b.	Zinc	1	2	9
(036)	c.	Silver	1	2	9
(037)	d.	Molybdenum	1	2	9
(038)	e.	Coal	1	2	9
(039)	f.	Limestone	1	2	9
(040)	g.	Clay	1	2	9
(041)	h.	Other	1	2	9

IF OTHER, SPECIFY: _____

112. Does any household member(s) that works in a mine or mining related job wear HIS/HER work clothing home after working?

(042)

1 = Always
2 = Sometimes
3 = Never
9 = DON'T KNOW

113. Does any household member(s) that works in a mine or mining related job come home from work without showering?

(043)

1 = Always
2 = Sometimes
3 = Never
9 = DON'T KNOW

HOUSE ID ___ ___ ___ ___

Next I have some questions about a number of activities you or other household members may do or may have done in the last three months. These include things you may have done for work, hobbies, or chores and at home or other places.

114. In the last 90 days, have any members of your household: (Circle all that apply)	Yes	No	Don't know	114a. Was this done at home, work, or elsewhere? HOME	OTHER	WORK/ BOTH	Don't know	..4B. IF WORK/OTHER: Were those clothes worn home? Yes	No	Don't know	Did he/she shower before coming home? Yes	No	Don't know
a. Painted pictures with artists paints? (not children's paints)	1	2 (044)	9	3	4 (045)	5	9	1	2 (046)	9	1	2 (047)	9
b. Painted, stained or refinished furniture?	1	2 (048)	9	3	4 (049)	5	9	1	2 (050)	9	1	2 (051)	9
c. Painted the inside or outside of a home or building?	1	2 (052)	9	3	4 (053)	5	9	1	2 (054)	9	1	2 (055)	9
d. Work with stained glass?	1	2 (056)	9	3	4 (057)	5	9	1	2 (058)	9	1	2 (059)	9
e. Cast lead into fishing sinkers, bullets or anything else?	1	2 (060)	9	3	4 (061)	5	9	1	2 (062)	9	1	2 (063)	9
f. Worked with soldering in electronics?	1	2 (064)	9	3	4 (065)	5	9	1	2 (066)	9	1	2 (067)	9
g. Soldering pipes or sheets of metal?	1	2 (068)	9	3	4 (069)	5	9	1	2 (070)	9	1	2 (071)	9
h. Repaired auto radiators?	1	2 (072)	9	3	4 (073)	5	9	1	2 (074)	9	1	2 (075)	9

HOUSE ID ___ ___ ___ ___

114. (Continued) In the last 90 days, have any members of your household: (Circle all that apply)	Yes	No	Don't know	114a. Was this done at home, work, or elsewhere? HOME	WORK/ OTHER	BOTH	Don't know	114B. IF WORK/OTHER: Were those clothes worn home? Yes	No	Don't know	Did he/she shower before coming home? Yes	No	Don't know
i. Worked on auto bodies or auto maintenance? (includes mechanics)	1	2 (076)	9	3	4 (077)	5	9	1	2 (078)	9	1	2 (079)	9
j. Worked at a sewage treatment plant?	1	2 (080)	9	3	4 (081)	5	9	1	2 (082)	9	1	2 (083)	9
k. Made pottery?	1	2 (084)	9	3	4 (085)	5	9	1	2 (086)	9	1	2 (087)	9
l. Ridden a dirt bike, mountain bike or ATV in the local area?	1	2 (088)	9	3	4 (089)	5	9	1	2 (090)	9	1	2 (091)	9
m. Welding?	1	2 (092)	9	3	4 (093)	5	9	1	2 (094)	9	1	2 (095)	9
n. Cleaned or repaired firearms?	1	2 (096)	9	3	4 (097)	5	9	1	2 (098)	9	1	2 (099)	9
o. Visited indoor firearm target ranges?	1	2 (100)	9	3	4 (101)	5	9	1	2 (102)	9	1	2 (103)	9
p. Wire/cable cutting or splicing?	1	2 (104)	9	3	4 (105)	5	9	1	2 (106)	9	1	2 (107)	9
q. Casting or smelting lead?	1	2 (108)	9	3	4 (109)	5	9	1	2 (110)	9	1	2 (111)	9

HOUSE ID ___ ___ ___ ___

114. (Continued) In the last 90 days, have any members of your household: (Circle all that apply)	Yes	No	Don't know	114a. Was this done at home, work, or elsewhere? HOME	WORK/ OTHER	BOTH	Don't know	114B. IF WORK/OTHER: Were those clothes worn home? Yes	No	Don't know	Did he/she shower before coming home? Yes	No	Don't know
r. Plastics manufacture?	1	2 (112)	9	3	4 (113)	5	9	1	2 (114)	9	1	2 (115)	9
s. Battery manufacture?	1	2 (116)	9	3	4 (117)	5	9	1	2 (118)	9	1	2 (119)	9
t. Pipe machining?	1	2 (120)	9	3	4 (121)	5	9	1	2 (122)	9	1	2 (123)	9
u. Electroplating with lead solutions?	1	2 (124)	9	3	4 (125)	5	9	1	2 (126)	9	1	2 (127)	9
v. Refining gasoline?	1	2 (128)	9	3	4 (129)	5	9	1	2 (130)	9	1	2 (131)	9
w. Paint, glaze, and ink manufacture?	1	2 (132)	9	3	4 (133)	5	9	1	2 (134)	9	1	2 (135)	9
x. Rubber manufacture?	1	2 (136)	9	3	4 (137)	5	9	1	2 (138)	9	1	2 (139)	9
y. Scrap metal recovery?	1	2 (140)	9	3	4 (141)	5	9	1	2 (142)	9	1	2 (143)	9
z1. Other lead related job or activity? SPECIFY_____	1	2 (144)	9	3	4 (145)	5	9	1	2 (146)	9	1	2 (147)	9
z2. Other cadmium related job or activity? SPECIFY_____	1	2 (148)	9	3	4 (149)	5	9	1	2 (150)	9	1	2 (151)	9

Now I'd like to ask you some questions about your diet and food preparation:

115. When food or drinks are prepared, served, or stored, are they often placed in clay pottery or ceramic dishes which were homemade or made in another country?

(152)
1 = Yes
2 = No
9 = DON'T KNOW

116. When food or drinks are prepared, served, or stored, are they often placed in copper or pewter dishes or containers?

(153)
1 = Yes
2 = No
9 = DON'T KNOW

117. When food or drinks are stored or put away, are they sometimes stored in the original can after being opened?

(154)
1 = Yes
2 = No
9 = DON'T KNOW

Now I have a few other questions about your household.

118. Does anyone smoke in your/SUBJECT'S home?

(155)
1 = Yes
2 = No (GO TO 121)
9 = DON'T KNOW

119. How many people smoke in this home? (including regular visitors/babysitters)

(156-157) ___ ___ (number of people)
(99 = DON'T KNOW)

120. Does anyone smoke TOBACCO PRODUCT in your/SUBJECT's home?

(Circle responses).

		Yes	No	Don't know	IF YES, How many:
(158)	a.Cigarettes	1	2	9	___ ___ (159-160) Cigarettes per day in the house? (1 pack=20)
(161)	b.Cigars	1	2	9	___ ___ (162-163) Cigars per day in the house?
(164)	c.Pipes	1	2	9	___ ___ (165-166) Pipe bowls per day in the house?

121. Do you have any dogs or cats that go in and out of the house?

(167)
1 = Yes
2 = No
9 = DON'T KNOW

If yes, specify number _____

122. Has anyone ever used any materials from mines or smelters, such as chat or slag, or lead industry material in or around your house or yard?

(168)
1 = Yes
2 = No
9 = DON'T KNOW

IF YES, SPECIFY WHAT MATERIALS AND HOW THEY WERE USED:

_____

_____

123. What is the highest year of education that was completed by the head of this household? (RESPONDENT MUST DECIDE WHO HEAD OF HOUSEHOLD IS)

(169-171) (circle one)

No Schooling	000
Elementary School	001 002 003 004 005 006 007 008
High School (GED=012)	009 010 011 012
Technical or Trade School	T13 T14
Junior or Community College	J13 J14
Four year College or University	013 014 015 016
Attended Graduate School (or higher)	017
REFUSED TO ANSWER	088
DON'T KNOW	099

(172) 124. What is your total, gross household income before taxes?

01 =$4,999 or less	07 =$30,000 to $34,999
02 =$5,000 to $9,999	08 =$35,000 to $39,999
03 =$10,000 to $14,999	09 =$40,000 or more
04 =$15,000 to $19,999	88 = REFUSED TO ANSWER
05 =$20,000 to $24,999	99 = DON'T KNOW
06 =$25,000 to $29,999	

Now we have a set of questions to ask about (SUBJECT'S NAME)

IF PARTICIPANT IS 6 - 71 MONTHS OF AGE, THEN GO TO SECTION 200.

IF PARTICIPANT IS 6 - 14 YEARS OF AGE, GO TO SECTION 300

IF PARTICIPANT IS 15 YEARS OF AGE OR OLDER, GO TO SECTION 400

200 CHILD QUESTIONNAIRE
AGE 6 - 71 MONTHS

HOUSE ID ___ ___ ___ ___

PERSON ID ___ ___ ___ ___ - ___ ___ ___ ___

QUESTIONS ABOUT THE CHILD 6 - 71 MONTHS OLD (LESS THAN 6 YEARS OLD) SHOULD BE ANSWERED BY THE PARENT OR LEGAL GUARDIAN OF THE CHILD.

Child's full legal name:_____

(005-012) PERSON ID ___ ___ ___ ___-___ ___ ___ ___

Now I need to ask a number of questions about (CHILD'S NAME).

(013) 201. Who is answering these questions?
1 = Child's mother
2 = Child's father
3 = Child's grandparent
4 = Child's other relative
5 = Other _____

202 How long has (subject's name) been living in this home?

Years ___ ___ (014-015) Months ___ ___ (016-117)

IF LESS THAN 90 DAYS, OBTAIN PREVIOUS ADDRESS.

Address: ----------

---

203. What is (CHILD'S NAME) date of birth?
(018-023) (MO/DA/YR) ___ ___ /___ ___ /___ ___
88 = REFUSED
99 = DON'T KNOW

204. Is (CHILD'S NAME) a boy or girl?
(024) 1 = Male
2 = Female

205. Which of the following best describes HIS/HER racial background?
(025) 1 = White
2 = Black
3 = Asian or Pacific Islander
4 = American Indian/Alaska native
8 = REFUSED
9 = DON'T KNOW

206. Is this child Hispanic or of Spanish origin or descent?
(026) 1 = Yes
2 = No
8 = REFUSED
9 = DON'T KNOW

IF CHILD LESS THAN 3 YEARS OLD:

(027) 207. Does this child breast feed?
1 = Yes
2 = No
7 = Not applicable, over 3 years old
8 = REFUSED
9 = DON'T KNOW

208. In the last 90 days, where does (CHILD'S NAME) usually spend HIS time each 24 hour period? (approximate number of hours)
(99 = DON'T KNOW)

	Babysitter (outside of home)	Day Care (commercial facility)	Other Location	Home	Total (24 hrs)
Monday	(028-029)	(030-031)	(032-033)	(034-035)	(036-037)
Tuesday	(038-039)	(040-041)	(042-043)	(044-045)	(046-047)
Wednesday	(048-049)	(050-051)	(052-053)	(054-055)	(056-057)
Thursday	(058-059)	(060-061)	(062-063)	(064-065)	(066-067)
Friday	(068-069)	(070-071)	(072-073)	(074-075)	(076-077)
Saturday	(078-079)	(080-081)	(082-083)	(084-085)	(086-087)
Sunday	(088-089)	(090-091)	(092-093)	(094-095)	(096-097)

209. How many hours, on average, does CHILD spend sleeping?

(098-099) ___ ___ (99 = DON'T KNOW)

210. How many hours during the day do you think (CHILD'S NAME) usually spends playing on the floor when indoors in this home?

(100-101) ___ Hours (99 = DON'T KNOW)

(102) 211. Does (CHILD'S NAME) play outdoors around the house or in the neighborhood?

1 = Yes
2 = No (GO TO QUESTION 217)
9 = DON'T KNOW (GO TO QUESTION 217)

212 IF YES, then how many hours a day on the average does (CHILD'S NAME) play outdoors?

(103-104) ___ ___ Hours 99 = DON'T KNOW

213. Where does (CHILD'S NAME) usually play when outdoors around the house? CIRCLE ONE

(105)
1 = Back yard
2 = Front yard
3 = Side yard
7 = Other (specify)_____
9 = DON'T KNOW

214. Where does (CHILD'S NAME) usually play outdoors (in the last 90 days) when he/she is not playing in your own home yard? CIRCLE ONE

(106-107)
01 = Neighbor's yard
02 = Playground
03 = Near or around creek or ditch
04 = On or near tailings or slag piles
05 = On sidewalks or streets
06 = Park
07 = Only plays at home
08 = Other (SPECIFY) _____
99 = DON'T KNOW

215. Is the ground where (CHILD'S NAME) usually plays mainly grassy, concrete/asphalt, plain dirt or soil, just a sandbox, or some other stuff? CIRCLE ONE

(108)
1 = Grassy
2 = Concrete/asphalt
3 = Dirt/soil
4 = Sandbox
7 = Other (SPECIFY)_____
9 = DON'T KNOW

216. Does (CHILD'S NAME) often take food, snacks, candy or a bottle or pacifier with him/her outside to play?

(109)
1 = Yes
2 = No
9 = DON'T KNOW

217. Are (CHILD'S NAME) hands or face usually washed before eating?
(110) 1 = Yes
2 = No
9 = DON'T KNOW

218. Are (CHILD'S NAME) hands or face usually washed before going to
(111) 1 = Yes
2 = No
9 = DON'T KNOW

219. Are (CHILD'S NAME) hands or face usually washed after playing wi
dirt or sand?
(112) 1 = Yes
2 = No
9 = DON'T KNOW

220. How many times is (CHILD'S NAME) bathed or given a shower?

(113-114) ___ ___ per week (99 = DON'T KNOW)

221. Has (CHILD'S NAME) used a pacifier in the last 6 months?
(115) 1 = Yes
2 = No
9 = DON'T KNOW

222. Does (CHILD'S NAME) suck HIS/HER thumb or fingers?
(116) 1 = Yes
2 = No
9 = DON'T KNOW

223. Does (CHILD'S NAME) chew on HIS/HER fingernails?
(117) 1 = Yes
2 = No
9 = DON'T KNOW

224. Does (CHILD'S NAME) have a favorite blanket or toy?
(118) 1 = Yes
2 = No (GO TO QUESTION 227)
9 = DON'T KNOW

225. Does (CHILD'S NAME) carry this around during the da
(119) 1 = Yes
2 = No
9 = DON'T KNOW

226 Does (CHILD'S NAME) often put this in HIS/HER mouth
(120) 1 = Yes
2 = No
9 = DON'T KNOW

227. Many children put some things other than food into their mouths. Would you say that (CHILD'S NAME):

(121)
1 = Does this a lot
2 = Just once in a while
3 = Almost never
4 = Never
9 = DON'T KNOW

228. Does (CHILD'S NAME) put HIS/HER mouth on furniture or on the window sill?

(122)
1 = Does this a lot
2 = Just once in a while
3 = Almost never
4 = Never
9 = DON'T KNOW

229 Sometimes children swallow things other than food. Would you say that (CHILD'S NAME) swallows things other than food?

(123)
1 = Does this a lot
2 = Just once in a while
3 = Almost never
4 = Never
9 = DON'T KNOW

If yes, specify items swallowed. ----------

230. Does (CHILD'S NAME) ever put paint chips in HIS/HER mouth?

(124)
1 = Does this a lot
2 = Just once in a while
3 = Almost never
4 = Never
9 = DON'T KNOW

231. Does your household have a vegetable garden in your yard?

(125)
1 = Yes
2 = No (GO TO 236)
9 = DON'T KNOW (GO TO 236)

232. Has soil been hauled in and placed on your garden?

(126)
1 = Yes
2 = No
9 = DON'T KNOW

IF YES, SPECIFY FROM WHERE? ----------

233. How often does (CHILD'S NAME) eat vegetables grown in your garden?

(127)

1 = Once a week or more
2 = Less than once per week
3 = Never (GO TO 236)
9 = DON'T KNOW (GO TO 236)

234. How often does (CHILD'S NAME) eat leafy green vegetables, (such as lettuce or spinach) grown : your garden?

(128)

1 = Once a week or more
2 = Less than once per week
3 = Never
9 = DON'T KNOW

235. How often does (CHILD'S NAME) eat root vegetable (such as beets or turnips) grown in your garden?

(129)

1 = Once a week or more
2 = Less than once per week
3 = Never
9 = DON'T KNOW

236. How often does (CHILD'S NAME) eat vegetables grown elsewhere in the local area? (e.g. NEIGHBOR'S GARDEN OR LOCAL FARMERS MARKET)

(130)

1 = Once a week or more
2 = Less than once per week
3 = Never (GO TO 239)
9 = DON'T KNOW (GO TO 239)

237. How often does he/she eat leafy green vegetables, (su as lettuce or spinach) grown elsewhere in the area?

(131)

1 = Once a week or more
2 = Less than once per week
3 = Never
9 = DON'T KNOW

238. How :en does he/she eat root vegetables, (such as b or turnips) grown elsewhere in the area?

(132)

1 = Once a week or more
2 = Less than once per week
3 = Never
9 = DON'T KNOW

239. Has SUBJECT ever been treated with traditional, folk or herbal medications?

(133)

1 = Yes
2 = No
9 = DON'T KNOW

IF YES, What was the medicine called? _____

_____

END: This completes the questionnaire. Do you have any questions or comments about it?

_____

_____

_____

Thank you for your time.

PERSON ID _ _ _ _ _-_ _ _ _

YOUNG PERSON QUESTIONNAIRE
AGES 6 - 14 YEARS OLD

HOUSE ID _ _ _ _

PERSON ID_ _ _ _ _ _ _ _ _

QUESTIONS ABOUT THE CHILD 6-14 YEARS OLD MU$T BE ANSWERED BY THE PARENT OR LEG
GUARDIAN OF THE CHILD.

Child's full/legal name_____

(001-004) HOUSE ID ___ ___ ___ ___

(005-012) PERSON ID ___ ___ ___ ___ - ___ ___ ___ ___

I need to ask a number of questions about (CHILD'S NAME).

301. Who is answering these questions?

(013)
1 = child's mother
2 = child's father
3 = child's grandparent
4 = child's other relative
5 = Other _____

302. How long has (SUBJECT'S NAME) been living in this home?

Years ___ ___ (014-015) Months ___ ___ (016-017)

IF LESS THAN 90 DAYS, OBTAIN PREVIOUS ADDRESS (12 MONTH PERIOD).

Address: ----------

---

303 What is (CHILD'S NAME) date of birth?

(018-023) (MO/DA/YR) __ __/__ __/__ __
ENTER 88 FOR REFUSED
ENTER 99 FOR DON'T KNOW

304. Is (NAME) a boy or girl?

(024)
1 = Male
2 = Female

305. Which of the following best describes HIS/HER racial background?

(025)
1 = White
2 = Black
3 = Asian or Pacific Islander
4 = American Indian/Alaska native
8 = REFUSED
9 = DON'T KNOW

306. Is he/she Hispanic or of Spanish origin or descent?

(026)
1 = Yes
2 = No
8 = REFUSED
9 = DON'T KNOW

307. What is the highest year of education (CHILD'S NAME) has comple

(027-029)

	(circle one)
No Schooling	000
Elementary School	001 002 003 004 005 006 007 008
High School (GED = 012)	009 010 011 012
REFUSED TO ANSWER	088
DON'T KNOW	099

IF CHIL IS 12 YEARS OR OLDER ASK 308 ON SMOKING, OTHERWISE, GO TO 309

308. Does (CHILD'S NAME) smoke or use tobacco products?

(030)

1 = Yes
2 = No (GO TO 309)
8 = REFUSED (GO TO 309)
9 = DON'T KNOW (GO TO 309)

Does he/she smoke/use TOBACCO PRODUCT?
(Circle responses)

			Yes	No	Don't know	IF YES, HOW MANY:
(031)	a.	Cigarettes	1	2	9	___ ___ Cigarettes per day, tot (032-033) (1 pack=20)
(034)	b.	Cigars	1	2	9	___ ___ Cigars per day, total (035-036)
(037)	c.	Pipes	1	2	9	___ ___ Pipe bowls per day, tot (038-039)
(040)	d.	Smokeless tobacco	1	2	9	___ ___ Times per day, total (041-042)

309. In the last 90 days, where does (CHILD'S NAME) usually spend HIS/HER time each 24 hour period? (approximate number of hours) (99 = DON'T KNOW)

	School	Babysitter (outside of home)	Day Care (commercial facility)	Other Location	Home	Total (24 h)
Monday	(043-044)	(045-046)	(047-048)	(049-050)	(051-052)	(053-054)
Tuesday	(055-056)	(057-058)	(059-060)	(061-062)	(063-064)	(065-066)
Wednesday	(067-068)	(069-070)	(071-072)	(073-074)	(075-076)	(077-078)
Thursday	(079-080)	(081-082)	(083-084)	(085-086)	(087-088)	(089-090)
Friday	(091-092)	(093-094)	(095-096)	(097-098)	(099-100)	(101-102)
Saturday	(103-104)	(105-106)	(107-108)	(109-110)	(111-112)	(113-114)
Sunday	(115-116)	(117-118)	(119-120)	(121-122)	(123-124)	(125-126)

310 How many hours a day does (CHILD'S NAME) spend sleeping?
(127) ___ ___ (99 = DON'T KNOW)

311. Does (CHILD'S NAME) play or spend time outdoors around the house or in the neighborhood?
(128)
1 = Yes
2 = No (GO TO QUESTION 317)
9 = DON'T KNOW (GO TO QUESTION 317)

312. If yes, then how many hours a day on the average does (CHILD'S NAME) play or spend time outdoors?

(129-130) ___ ___ Hours 99 = DON'T KNOW

313. Where does (CHILD'S NAME) usually play when outdoors around the house?

(131)

1 = Back yard
2 = Front yard
3 = Side yard
7 = Other (specify) _____
9 = DON'T KNOW

314. Where does (CHILD'S NAME) usually play outdoors (in the last 90 days) when he/she is not playing in your own home yard?

(132-133)

01 = Neighbor's yard
02 = Playground
03 = Near or around creek or ditch
04 = On or near tailings or slag piles
05 = On sidewalks or streets
06 = Park
07 = Only plays at home
08 = Other (SPECIFY) _____
99 = DON'T KNOW

315. Is the ground where (CHILD'S NAME) usually plays mainly grassy, concrete/asphalt, plain dirt or soil, just a sandbox, or some other stuff?

(134)

1 = Grassy
2 = Concrete/asphalt
3 = Dirt/soil
4 = Sandbox
7 = Other (SPECIFY) _____
9 = DON'T KNOW

316. Does (CHILD'S NAME) often take food or a drink with him/her outside to play?

(135)

1 = Yes
2 = No
9 = DON'T KNOW

317. Does (NAME) usually wash HIS/HER hands or face before eating?

(136)
1 = Yes
2 = No
9 = DON'T KNOW

318. Does (NAME) usually wash HIS/HER hands or face before going to sleep?

(137)
1 = Yes
2 = No
9 = DON'T KNOW

319. Does (NAME) usually wash HIS/HER hands or face after playing or working with dirt or sand?

(138)
1 = Yes
2 = No
9 = DON'T KNOW

320. Does (NAME) suck HIS/HER thumb or fingers?

(139)
1 = Yes
2 = No
9 = DON'T KNOW

321. Does (CHILD'S NAME) chew on HIS/HER fingernails?

(140)
1 = Yes
2 = No
9 = DON'T KNOW

322. Does (CHILD'S NAME) put things other than food in HIS/HER mouth?

(141)
1 = Yes
2 = No
9 = DON'T KNOW

IF YES, SPECIFY ----------

323. Sometimes children swallow things other than food. Would you say that (CHILD'S NAME) swallows things other than food:

(142)
1 = Does this a lot
2 = Just once in a while
3 = Almost never
4 = Never
9 = DON'T KNOW

IF YES, SPECIFY ----------

324. Does your household have a vegetable garden in your yard?

(143)
1 = Yes
2 = No (GO TO 329)
9 = DON'T KNOW (GO TO 329)

325. Has soil been hauled in and placed on your garden?

(144)
1 = Yes
2 = No
9 = DON'T KNOW

IF YES, SPECIFY FROM WHERE? ----------

326. How often does (CHILD'S NAME) eat vegetables grown in your garden?

(145)
1 = Once a week or more
2 = Less than once per week
3 = Never (GO TO 329)
9 = DON'T KNOW (GO TO 329)

327. How often does (CHILD'S NAME) eat leafy green vegetables, (such as lettuce or spinach) grown in your garden?

(146)
1 = Once a week or more
2 = Less than once per week
3 = Never
9 = DON'T KNOW

328. How often does (CHILD'S NAME) eat root vegetables, (such as beets or turnips) grown in your garden?

(147)
1 = Once a week or more
2 = Less than once per week
3 = Never
9 = DON'T KNOW

329. How often does (CHILD'S NAME) eat vegetables grown elsewhere in the local area? (e.g. NEIGHBOR'S GARDEN OR LOCAL FARMERS MARKET)

(148)

1 = Once a week or more
2 = Less than once per week
3 = Never (GO TO 332)
9 = DON'T KNOW (GO TO 332)

330. How often does he/she eat leafy green vegetables, (such as lettuce or spinach) grown elsewhere in the area?

(149)

1 = Once a week or more
2 = Less than once per week
3 = Never
9 = DON'T KNOW

331. How often does he/she eat root vegetables, (such as beets or turnips) grown elsewhere in the area?

(150)

1 = Once a week or more
2 = Less than once per week
3 = Never
9 = DON'T KNOW

332. Has SUBJECT ever been treated with traditional, folk or herbal medications?

(151)

1 = Yes
2 = No
9 = DON'T KNOW

IF YES, What was the medicine called? _____

_____

PERSON ID _ _ _ _ - _ _ _ _

My last questions are about (CHILD'S NAME'S) activities.

333. In the last 90 day, has (CHILD'S NAME) participated in any of the following activities? (Circle all that apply.)

			Yes	No	Don't know
(152)	a.	Painted pictures with artists paints? (not children's paints)	1	2	9
(153)	b.	Painted, stained or refinished furniture?	1	2	9
(154)	c.	Painted the inside or outside of a home or building?	1	2	9
(155)	d.	Worked with stained glass?	1	2	9
(156)	e.	Cast lead into fishing sinkers, bullets or anything else?	1	2	9
(157)	f.	Worked with soldering in electronics?	1	2	9
(158)	g.	Worked on soldering pipes or sheets of metal?	1	2	9
(159)	h.	Repaired auto radiators?	1	2	9
(160)	i.	Worked on auto bodies or auto maintenance?	1	2	9
(161)	j.	Made pottery?	1	2	9
(162)	k.	Ridden a dirt bike, mountain bike, or ATV in the local area?	1	2	9
(163)	l.	Welded?	1	2	9
(164)	m.	Visited indoor firearm target ranges?	1	2	9
(165)	n.	Cleaned or repaired firearms	1	2	9

This completes the questionnaire. Do you have any questions or comme about it?

_____

_____

Thank you for your time.

TEENAGE AND ADULT QUESTIONNAIRE
AGES 15 - 44 YEARS

QUESTIONS ABOUT THE YOUNG ADULT AGED 15-16 MUST BE ANSWERED WITH THE PARENT OR GUARDIAN PRESENT.

400. QUESTIONS FOR SELECTED PERSON AGE 15 - 44.

HOUSE ID ___ ___ ___ ___

PERSON ID ___ ___ ___ ___ - ___ ___ ___ ___

What is your full/legal name?

_____

(001-004) HOUSE ID ___ ___ ___ ___

(005-012) PERSON ID ___ ___ ___ ___ - ___ ___ ___ ___

40. WHO IS ANSWERING THESE QUESTIONS?
(013)
1 = self
2 = subject's mother
3 = subject's father
4 = subject's grandparent
5 = subject's other relative
6 = Other _____

401a. IF SELF IS ANSWERING, IS ANY OTHER FAMILY MEMBER PRESENT?
(014)
1 = yes
2 = no

402. How long have you (SUBJECT'S NAME) been living in this home?

Years ___ ___ (015-016) Months ___ ___ (017-118)

IF LESS THAN 90 DAYS, OBTAIN PREVIOUS ADDRESS.

Address: ----------

---

403. What is the your date of birth? ___ ___/___ ___/___ ___
(019-024) (MONTH / DAY / YEAR)
ENTER 88 = REFUSED
ENTER 99 = DON'T KNOW

404 SUBJECT'S GENDER
(circle one)
(025) 1 = Male 2 = Female

405. What is your race or ethnic group? (READ THE LIST)
(026)
1 = White
2 = Black
3 = Asian or Pacific Islander
4 = American Indian/Alaska native
8 = REFUSED
9 = DON'T KNOW

406. Are you Hispanic or of Spanish origin or descent?
(027)
1 = Yes
2 = No
8 = REFUSED
9 = DON'T KNOW

407 (028-030) What is the highest year of education you have completed?

	(circle one)
No Schooling	000
Elementary School	001 002 003 004 005 006 007 008
High School (GED = 012)	009 010 011 012
Technical or Trade School	T13 T14
Junior or Community College	J13 J14
Four year College or University	013 014 015 016
Graduate School (or higher)	017
REFUSED TO ANSWER	088
DON'T KNOW	099

PERSON ID _ _ _ _ - _ _ _ _

TOBACCO/ALCOHOL

The next questions concern tobacco and alcohol consumption.

408. Are you exposed to people smoking at your workplace in your imme work area?

(031)
1 = yes
2 = no
8 = REFUSED TO ANSWER
9 = DON'T KNOW

.09. Have you smoked at least 100 cigarettes during your entire life? (1 PACK = 20 CIGARETTES)

(032)
1 = yes
2 = no (GO TO QUESTION 410)
8 = REFUSED TO ANSWER
9 = DON'T KNOW

409.1 Do you smoke cigarettes now?

(033)
1 = yes (GO TO QUESTION 409.1.1)
2 = no (GO TO QUESTION 409.2)
8 = REFUSED TO ANSWER (GO TO 409.2)
9 = DON'T KNOW

409.1.1 On the average, how many cigarettes a c you now smoke?

(034-036) ___ ___ ___ (NOW GO TO QUESTION 409.3)

409.2 How long has it been since you smoked cigarettes?

(037-038) __ __ years
00 = under 1 year
88 = refused
99 = DON'T KNOW

409.3 On the average of the entire time you smoked, how m cigarettes did you smoke per day?

(039-040) __ __ cigarettes per day
88 = REFUSED
99 = DON'T KNOW

409.4 About how old were you when you first started smoki cigarettes regularly?

(041-042) __ __ years old
88 = REFUSED
99 = DON'T KNOW

409.5 For how many years WERE YOU/HAVE YOU BEEN a smoker, including the time you may have stayed off cigarett

(043-044) __ __ years
88 = REFUSED
99 = DON'T KNOW

CIGARS

410. Have you smoked at least 50 cigars during your entire life?

(045)
1 = yes
2 = no (GO TO QUESTION 411)
8 = REFUSED TO ANSWER
9 = DON'T KNOW

410.1 Do you smoke cigars now?

(046)
1 = yes
2 = no (GO TO QUESTION 410.2)
8 = REFUSED TO ANSWER (GO TO 410.2)
9 = DON'T KNOW

410.1.1 On the average, how many cigars a week do you now smoke?

(047-048) ___ ___ (NOW GO TO QUESTION 410.3)

410.2 How long has it been since you smoked cigars?

(049-050) ___ ___ years
00 = under 1 year
88 = REFUSED
99 = DON'T KNOW

410.3 On the average of the entire time you smoked, how many cigars did you smoke per week?

(051-052) ___ ___ cigars per week
88 = REFUSED
99 = DON'T KNOW

410.4 About how old were you when you first started smoking cigars regularly?

(053-054) ___ ___ years old
88 = REFUSED
99 = DON'T KNOW

410.5 For how many years WERE YOU/HAVE YOU BEEN a cigar smoker, not including the time you may have stayed off cigars?

(055-056, __ __ years
88 = REFUSED
99 = DON'T KNOW

PERSON ID _ _ _ _ _-_ _ _ _

PIPES

411. Have you smoked at least 50 pipes during your entire li[fe]

(057)
1 = yes
2 = no (GO TO QUESTION 412)
8 = REFUSED TO ANSWER
9 = DON'T KNOW

411.1 Do you smoke pipes now?

(058)
1 = yes (GO TO QUESTION 411.1.1)
2 = no (GO TO QUESTION 411.2)
8 = REFUSED TO ANSWER (GO TO 411.2)
9 = DON'T KNOW

411.1.1 On the average, how many pipes do you now smoke per week?

(059-060) ___ ___ (NOW GO TO QUESTION 411.3)

411.2 How long has it been since you smoked pipes?

(061-062) ___ ___ years
00 = under 1 year
88 = REFUSED
99 = DON'T KNOW

411.3 On the average of the entire time you smoked, how m[any] pipes did you smoke per week?

(063-064) ___ ___ pipes per week
88 = REFUSED
99 = DON'T KNOW

411.4 About how old were you when you first started s[moking] pipes regularly?

(065-066) ___ ___ years old
88 = REFUSED
99 = DON'T KNOW

411.5 For how many years WERE YOU/HAVE YOU BEEN a pipe s[moker], not including the time you may have stayed off pipe

(067-068) __ __ years
88 = REFUSED
99 = DON'T KNOW

CHEWING TOBACCO

412. Have you used chewing tobacco at least 20 or more times during your entire life?

(069)
1 = yes
2 = no (GO TO QUESTION 413)
8 = REFUSED TO ANSWER
9 = DON'T KNOW

412.1 Do you chew tobacco now?

(070)
1 = yes
2 = no (GO TO QUESTION 412.2)
8 = REFUSED TO ANSWER (GO TO 412.2)
9 = DON'T KNOW

412.1.1 On the average, how many plugs, twists, or pouches do you chew a week?

(071-072) ___ ___ (NOW GO TO QUESTION 412.3)

412.2 How long has it been since you chewed tobacco?

(073-074) __ __ years
00 = under 1 year
88 = REFUSED
99 = DON'T KNOW

412.3 On the average of the entire time you chewed tobacco, how many plugs/twists/or pouches did you chew a week?

(075-076) ___ ___ per week
88 = REFUSED
99 = DON'T KNOW

412.4 About how old were you when you first started chewing tobacco regularly?

(077-078) __ __ years old
88 = REFUSED
99 = DON'T KNOW

412.5 For how many years HAVE YOU/DID YOU chew tobacco, not including the time you may have stayed off chewing tobacco?

(079-080) __ __ years
88 = REFUSED
99 = DON'T KNOW

PERSON ID _ _ _ _ _-_ _ _ _

SNUFF

413. Have you used snuff at least 20 or more times during yo entire life?

(081)
1 = yes
2 = no (GO TO QUESTION 414)
8 = REFUSED TO ANSWER
9 = DON'T KNOW

413.1 Do you use snuff now?

(082)
1 = yes (GO TO QUESTION 413.1.1)
2 = no (GO TO QUESTION 413.2)
8 = REFUSED TO ANSWER (GO TO 413.2)
9 = DON'T KNOW

413.1.1 On the average, how many cans/tins/or of snuff do you use a week?

(083-084) ___ ___ (NOW GO TO QUESTION 413.3)

413.2 How long has it been since you used snuff?

(085-086) ___ ___ years
00 = under 1 year
88 = REFUSED
99 = DON'T KNOW

413.3 On the average of the entire time you used snuf how many cans/tins/or pouches did you use a wee

(087-088) ___ ___ per week
88 = REFUSED
99 = DON'T KNOW

413.4 About how old were you when you first starte snuff regularly?

(089-090) ___ ___ years old
88 = REFUSED
99 = DON'T KNOW

413.5 For how many years HAVE YOU/DID YOU use snuff, including the time you may have stayed off snuf

(091-092) ___ ___ years
88 = REFUSED
99 = DON'T KNOW

Now I have a few questions on alcohol consumption.

414. Did you ever drink alcoholic beverages?

(093)
1 = Yes
2 = No (GO TO QUESTION 415)
8 = REFUSED
9 = DON'T KNOW

414.1 Do you presently drink alcoholic beverages?

(094)
1 = Yes (GO TO QUESTION 414.1.2)
2 = No
8 = REFUSED TO ANSWER (GO TO QUESTION 415)
9 = DON'T KNOW (GO TO QUESTION 415)

414.1.1 How old were you when you quit?

(095-096) ___ ___
88 = REFUSED TO ANSWER
99 = DON'T KNOW

414.1.2 How old were you when you began drinking alcoholic beverages?

(097-098) ___ ___
88 = REFUSED TO ANSWER
99 = DON'T KNOW

414.1.3 On the average, how many drinks a week do you have? (1 DRINK = 1 BEER, 1 SHOT LIQUOR OR MOONSHINE, 1 GLASS WINE OR WINE COOLER)

(099-100) ___ ___
88 = REFUSED TO ANSWER
99 = DON'T KNOW
LESS THAN 1/week = 00

PERSON ID _ _ _ _-_ _ _ _

415. Now I would like to know where you spend your time each 24 hour perio between school, home, work, or some other location, in the last 90 d (approximate number of hours; 99 = DON'T KNOW)

	School	Work	Other Location	Home	Total (24hr)
Monday	(101-102)	(103-104)	(105-106)	(107-108)	(109-110)
Tuesday	(111-112)	(113-114)	(115-116)	(117-118)	(119-120)
Wednesday	(121-122)	(123-124)	(125-126)	(127-128)	(129-130)
Thursday	(131-132)	(133-134)	(135-136)	(137-138)	(139-140)
Friday	(141-142)	(143-144)	(145-146)	(147-148)	(149-150)
Saturday	(151-152)	(153-154)	(155-156)	(157-158)	(159-160)
Sunday	(161-162)	(163-164)	(165-166)	(167-168)	(169-170)

The next set of questions are about activities and jobs you may have.

416. In the last 90 days have you worked as a miner or in a mining related job such as mine material handling or transportation?

(171)
1 = Yes
2 = No (GO TO 423)
9 = DON'T KNOW (GO TO 423)

417. What type of mine work did you do in the last 90 days? (Circle all that apply.)

			Yes	No	DON'T KNOW
(172)	a.	Underground	1	2	9
(173)	b.	Surface	1	2	9
(174)	c.	Milling	1	2	9
(175)	d.	Transportation/ handling	1	2	9
(176)	e.	Clerical/Admin.	1	2	9
(177)	f.	Smelter	1	2	9
(178)	g.	Other	1	2	9

IF OTHER, specify: _____

418. What type of mine did you work in the last 90 days? (Circle all that apply.)

			Yes	No	Don't know
(179)	a.	Lead	1	2	9
(180)	b.	Zinc	1	2	9
(181)	c.	Silver	1	2	9
(182)	d.	Molybdenum	1	2	9
(183)	e.	Coal	1	2	9
(184)	f.	Limestone	1	2	9
(185)	g.	Clay	1	2	9
(186)	h.	Other	1	2	9

IF OTHER, SPECIFY: _____

419. What is the name of the place where you work (have worked)?

---

420. How long have you worked (did you work) there, in years and months?

___ ___ Years (187-188) ___ ___ Months (189-190)

421. Do (did) you change out of your work clothes and leave them at work?

(191)
1 = Always
2 = Sometimes
3 = Never
9 = DON'T KNOW

422. Do (did) you shower at work before coming home?

(192)
1 = Always
2 = Sometimes
3 = Never
9 = DON'T KNOW

PERSON ID _ _ _ _ _-_ _ _ _

423. In the last 90 days, have you done any of the following activities? (Circle all that apply)

		Yes	No	Don't know
(193)	a. Painted pictures with artists paints? (not children's paints)	1	2	9
(194)	b. Painted, stained or refinished furniture?	1	2	9
(195)	c. Painted the inside or outside of a home or building?	1	2	9
(196)	d. Worked with stained glass?	1	2	9
(197)	e. Cast lead into fishing sinkers, bullets or anything else?	1	2	9
(198)	f. Worked with soldering in electronics?	1	2	9
(199)	g. Worked on soldering pipes or sheets of metal?	1	2	9
(200)	h. Repaired radiators?	1	2	9
(201)	i. Worked on auto bodies or auto maintenance?	1	2	9
(202)	j. Worked at a sewage treatment plant?	1	2	9
(203)	k. Made pottery?	1	2	9
(204)	l. Ridden a dirt bike, mountain bike, or ATV in the local area?	1	2	9
(205)	m. Welding?	1	2	9
(206)	n. Visited indoor firearm target ranges?	1	2	9
(207)	o. Cleaned or repaired firearms?	1	2	9
(208)	p. Wire or cable cutting or splicing?	1	2	9
(209)	q. Casting or smelting lead?	1	2	9
(210)	r. Plastics manufacture?	1	2	9
(211)	s. Battery manufacture?	1	2	9
(212)	t. Pipe machining?	1	2	9
(213)	u. Electroplating with lead solutions?	1	2	9
(214)	v. Refining gasoline?	1	2	9

(215)	w. Paint, glaze, and ink manufacture?	1	2	9
(216)	x. Rubber manufacture?	1	2	9
(217)	y. Scrap metal recovery?	1	2	9
(218)	z1. Other lead related job or activity?	1	2	9

SPECIFY_____

(219)	z2. Other cadmium related job or activity	1	2	9

SPECIFY_____

424. Have you done any of the following activities in the last month?

		Yes	No
(220)	a. Painted a house or building inside or out?	1	2
(221)	b. Painted or refinished furniture?	1	2

PERSON ID _ _ _ _ - _ _ _ _

OCCUPATIONS

425. Now I'd like to ask about your two most recent jobs, starting with the (Unemployed or retired or housewife should be entered as a job.)

a. What type of industry is/was this?
b. What is/was your job title and a description of what you do?
c. When did you work there?

	a. TYPE OF INDUSTRY	b. TITLE & DESCRIPTION	c. TIME FROM (MO/YR)	TO (MO/YR)
425.1	_____ _____ _____ _____ (222-225)	_____ _____ _____ _____ (226-229)	_ _/_ _ (230-233)	_ _/_ _ (234-237)
425.2	_____ _____ _____ _____ (238-241)	_____ _____ _____ _____ (242-245)	_ _/_ _ (246-249)	_ _/_ _ (250-253)

(254-257) 426. What is the job title you have had <u>most</u> of the time you have worked in the last 90 days?

_____
_ _ _ _

(258-261) 427. What is the job title you have had <u>most</u> of the time you have worked in the last year?

_____
_ _ _ _

428. Does your household have a garden in your yard? (VEGETABLE OR FLOWER)

(252)
1 = Yes
2 = No (GO TO 434)
9 = DON'T KNOW (GO TO 434)

429. IF YES, Do you frequently till, plant or work the garden yourself?

(253)
1 = Yes
2 = No
9 = DON'T KNOW

430. Has soil been hauled in and placed on your garden?

(264)
1 = Yes
2 = No
9 = DON'T KNOW
IF YES, Specify from where _____

431. How often do you eat vegetables grown in your garden?

(265)
1 = Once a week or more
2 = Less than once per week
3 = Never (GO TO 434)
9 = DON'T KNOW (GO TO 434)

432. How often do you eat leafy green vegetables, (such as lettuce or spinach) grown in your garden?

(266)
1 = Once a week or more
2 = Less than once per week
3 = Never
9 = DON'T KNOW

433. How often do you eat root vegetables, (such as beets or turnips) grown in your garden?

(267)
1 = Once a week or more
2 = Less than once per week
3 = Never
9 = DON'T KNOW

434. How often do you eat vegetables grown elsewhere in the local area? (e.g. NEIGHBOR'S GARDEN OR LOCAL FARMER'S MARKET)

(268)
1 = Once a week or more
2 = Less than once per week
3 = Never (GO TO 437)
9 = DON'T KNOW (GO TO 437)

435. How often do you eat leafy green vegetables, (such as lettuce or spinach) grown elsewhere in the area?

(269)
1 = Once a week or more
2 = Less than once per week
3 = Never
9 = DON'T KNOW

436. How often do you eat root vegetables, (such as beets o: turnips) grown elsewhere in the area?

(270)
1 = Once a week or more
2 = Less than once per week
3 = Never
9 = DON'T KNOW

437. Have you ever been treated with traditional, folk, or herbal medications?

(271)
1 = Yes
2 = No
9 = DON'T KNOW

IF YES, What was the medicine called? _____

_____

PERSON ID _ _ _ _ _-_ _ _ _

MEN: GO TO END

FOR WOMEN ONLY:

Now I have a couple questions on pregnancy and birth control pills. I ask these questions because they can affect the results of the blood tests we will be doing.

438. Are you pregnant?
(272) 1 = Yes (GO TO END)
2 = No
7 = Not applicable (male subject)
8 = REFUSED
9 = DON'T KNOW

439. Are you taking birth control pills?
(273) 1 = Yes
2 = No
7 = Not applicable (male subject or 438 answered YES)
8 = REFUSED
9 = DON'T KNOW

END:

This completes the questionnaire. Do you have any questions or comments about it?

_____

_____

_____ _____

_____

Thank you for your time.

Appendix D—MRI (Midwest Research Institute) Report

MRI REPORT

Multistate Lead and Cadmium Exposure Study with the States of Missouri, Kansas, and Illinois

Summary Report

For Agency for Toxic Substances and Disease Registry (ATSDR)

Contract No. 205-90-0839
Work Authorization No. 1

MRI Project No. 9723-A

March 2, 1992

MIDWEST RESEARCH INSTITUTE 425 Volker Boulevard, Kansas City, MO 64110-2299 • (816) 753-7600

SECTION 1

EXECUTIVE SUMMARY

1.1 BACKGROUND

The Agency for Toxic Substances and Disease Registry (ATSDR) developed a multisite approach to examine the interdependence between environmental contaminant sources, human behavior, and socioeconomic factors that may influence blood lead levels in susceptible populations.

Three sites on the National Priority List (NPL) came to the attention of ATSDR as areas where residents require additional health evaluations. Lead and cadmium are the contaminants of specific concern. The NPL's sites included in this study are (1) Joplin, Jasper County, Missouri; (2) Cherokee County Subsite in Galena, Kansas; and (3) NL Industries/Taracorp Site in Granite City, Madison County, Illinois. The primary media and route for potential exposure at each of these sites are high soil concentrations of lead and cadmium.

Health officials in each of the three states represented agreed to participate in conducting exposure studies to assess the degree to which residents were being exposed. The similarity in study design for the three sites made it feasible to include the individual studies in a larger multisite study approach. During the months of November 1990 through March 1991, ATSDR met with representatives and officials from the three State Departments of Health who agreed to participate in the Multistate Study.

1.2 OBJECTIVES

ATSDR, through Contract No. 205-90-0839, assigned Midwest Research Institute (MRI) the responsibility to provide laboratory services and support the collection of biological data for the Multistate Study. MRI's objectives for the project were:

- To collect, process, store, and transport blood and urine specimens from study participants to the Centers for Disease Control/Center for Environmental Health and Injury Control (CDC/CEHIC) for analysis for lead, cadmium, free erythrocyte protoporphyrin (FEP), alanine-amino

peptidase (AAP), gamma-glutamyltransferase (GGT), *N*-acetyl β-glucosamindase (NAGA), creatinine, and several immunological indicators.

- To provide analysis services for routine blood and urine tests, using local hospitals and Roche Biomedical Laboratories (Roche) in Kansas City, Missouri.

- To implement a Quality Assurance/Quality Control (QA/QC) program to assess the quality of the data from the routine blood and urine tests and to provide comprehensive and traceable data to ATSDR.

1.3 SUMMARY OF RESULTS

MRI supplied qualified personnel to collect blood and urine specimens from 1,705 study participants at the three study sites and to process, store, and transport the specimens for the analytical tests shown in Tables 1 and 2. The sites, number of participants, and dates of collection were as follows:

Site	Number of participants	Dates of collection
Joplin, Missouri	701	July 16-August 27, 1991
Galena, Kansas	163	September 10-30, 1991
Granite City, Illinois	841	August 22-September 20, 1991

Summaries of the number of specimens collected for specific tests are shown in Tables 3 and 4. Control and replicate specimens were generated at the rates of 15% and 10%, respectively, of the number of participants for the routine blood and urine tests shown in Table 4. Table 5 is a summary of the number of specimens generated for each QA/QC specimen type.

1.4 ORGANIZATION OF REPORT

- The remainder of this report provides detail on project organization (Section 2); preliminary activities (Section 3); collection, processing, storage, and transport of specimens (Section 4); analysis activities (Section 5); and collection, analysis, and QC results (Section 6). The Appendices contain the CDC/CEHIC laboratory protocol, examples of documentation forms, and detailed collection results and QC data for the control and replicate specimens.

Table 1. BLOOD SPECIMEN COLLECTION

Blood tests	Collection tube type	No. of tubes	Volume required	Special handling	Shipping instructions
Lead[a]	EDTA	[b]	0.5 mL	4°C	Overnight/batch
Cadmium[a]	EDTA	[b]	0.5 mL	4°C	Overnight/batch
FEP[a]	EDTA	[b]	0.5 mL	4°C	Overnight/batch
CBC[c]	EDTA	1	1 mL	8 h/on ice	Local/daily
Immunoglobulin[a]	Red top	[d]	—	Freeze	Overnight/batch
Biomedical tests[•]	Red top	[d]	3 mL	4°C	Overnight/batch
Immune panel[a]	Heparinized	1	1.5 mL	Control room temp.	Overnight/daily
Total volume			7.0 mL		

[a] Analysis by CDC/CEHIC.
[b] One tube was used to collect the blood for Pb, Cd, and FEP.
[c] Analysis by local hospital laboratories.
[d] One tube was used to collect the blood for the IgG and biomedical tests.
[•] Analysis by Roche Biomedical Laboratories.

Notes:
A. Tests listed by priority for collection and analysis.
B. Syringe and butterfly/vacutainer apparatus was used to collect specimens from children ages 6 mo through 6 yr old.
C. The immunoglobulin test was performed from a 0.5-mL aliquot of the serum collected for the biomedical tests.

Table 2. URINE SPECIMEN COLLECTION

Analyte	Specimen	Volume	Preparation
Cadmium[a]	On-site void	10 mL	HNO_3
GGT/AAP[a]	On-site void	10 mL	Glycerol
NAGA[a]	On-site void	5 mL	No preservative
Creatinine[a]	On-site void	5 mL	No preservative
Urinalysis[b]	On-site void	5 mL	No preservative

[a] Frozen immediately (–20°C), stored, and shipped with dry ice overnight. Analysis by CDC/CEHIC.

[b] Stored at 4°C. Analysis by local hospital laboratories.

SECTION 2

PROJECT ORGANIZATION

Midwest Research Institute (MRI) worked with ATSDR and the Principal Investigators (PIs) from each of the states to plan, coordinate, and conduct the Multistate Study. The overall project organization is shown in Figure 1.

As cited previously, MRI's responsibilities included collecting, processing, storing, and transporting blood and urine specimens to the various laboratories for specific chemical and biomedical analyses, implementing a QA/QC program that was initiated at the collection site, and providing comprehensive and traceable data to ATSDR.

Specific activities performed by MRI to achieve the objectives of the Multistate Study included:

- Providing qualified personnel to work at each study site to collect, process, store, and transport blood and urine specimens as specified in the Revised Work Plan. Phlebotomists and lab staff were recruited near the study sites to perform this work.
- Contracting with Roche Biomedical Laboratories (Roche) to perform the blood chemistry panel specified in the Revised Work Plan.
- Contracting with a hospital laboratory near each site to perform complete blood counts (CBC) and routine urinalyses (UA) for all specimens.
- Coordinating all collection activities with the Missouri, Kansas, and Illinois Departments of Health Principal Investigators (PIs).
- Applying QA/QC procedures to maintain specimen integrity, and providing control specimens and replicate analyses as required.
- Providing appropriate documentation to track all specimens (using a unique ID number) through collection, processing, storage, and transport.
- Transporting all specimens to CDC/CEHIC, Roche, and local hospital laboratories for analysis under specified storage conditions.

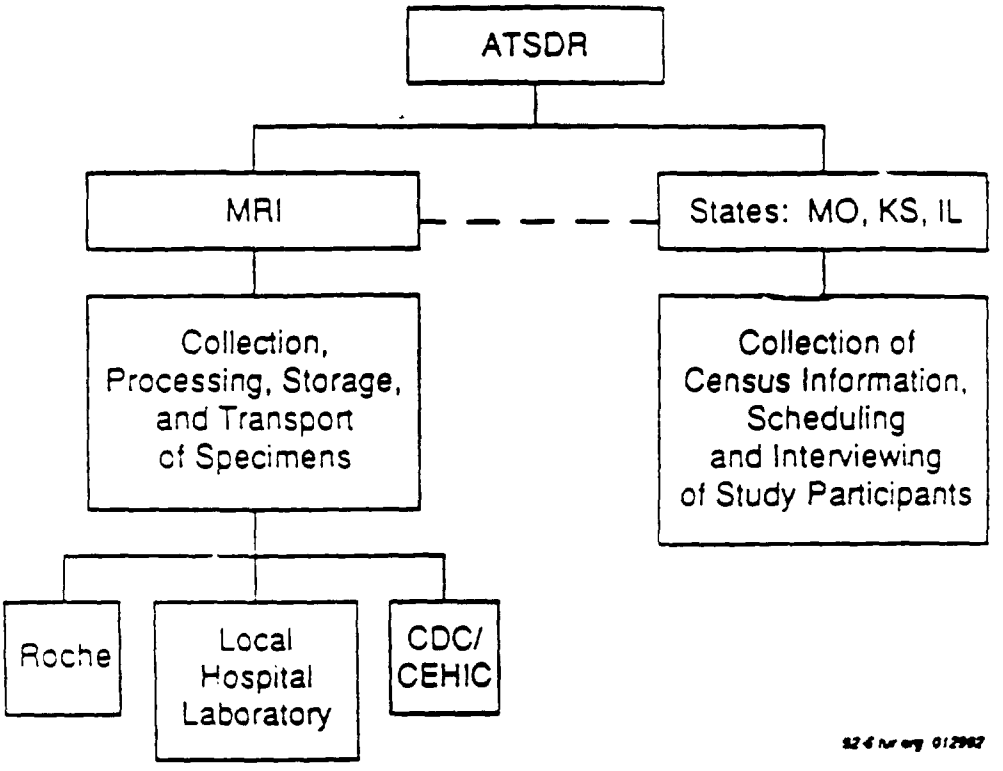


Figure 1. Overall project organization.

- Providing analysis results by unique ID number for each specimen to ATSDR for the routine blood and urine tests and biomedical tests. The test results provided by the local laboratories and Roche were reported to MRI, reviewed, compiled, and transferred by magnetic tape to ATSDR.

MRI's day-to-day project management included the following responsibilities:

- Daily contact with the on-site coordinator and PI.
- Receipt of copies of collection and shipping summaries.
- Receipt, review, and compilation of hard copy analysis results from Roche and local hospital laboratories.
- Evaluation of blind QC results received with each set of analysis results.
- Transcription of hard copy data onto a magnetic tape.
- Reporting status of the project to the ATSDR project officer in required weekly and monthly reports and as needed.

SECTION 3

PRELIMINARY ACTIVITIES

Several planning meetings were held with ATSDR, States, MRI, and CDC/CEHIC staff between November 1990 and initiation of the study, including a planning meeting in Atlanta in March 1991, which was attended by staff from all the agencies. These meetings were held to clarify the work and to define the responsibilities of all agencies involved in the Multistate Study. MRI prepared a work plan for the Multistate Study in response to a work assignment request from ATSDR dated April 8, 1991. MRI's work plan was reviewed by ATSDR and subsequently revised to address specific comments. MRI's work plan dated May 24, 1991 was followed throughout the Multistate Study. A laboratory protocol for collection, processing, storage, and transport of specimens was supplied by CDC/CEHIC and is included as Appendix A.

Planning meetings were also conducted by MRI with local hospitals, Roche, local labor resources, and couriers/shippers to arrange analysis services, labor, and transport of specimens for the Multistate Study. These planning meetings included prestudy site visits to evaluate collection facilities and shipping logistics. Preliminary trials were conducted immediately before collection dates to ensure that all personnel were properly trained.

Data management was planned in conjunction with the ATSDR Project Officer and Data Manager. A meeting was held at MRI on July 10, 1991, to discuss the data management requirements, and subsequent planning with a local transcription service followed. A test tape containing results from the CBC, UA, and blood chemistry tests was submitted to ATSDR on September 17, 1991, and was approved on September 30, 1991.

Additional details on the preliminary activities for each study site follow.

SECTION 4

COLLECTION, PROCESSING, STORAGE, AND TRANSPORT OF SPECIMENS

Specimens were collected, processed, stored, and transported according to the laboratory protocol supplied by CDC/CEHIC (Appendix A). Specific information regarding staff, facilities, supplies, scheduling, storage, and transport follows.

4.1 ON-SITE STAFF

Phlebotomy support was arranged through Roche for the Joplin, Missouri, and Galena, Kansas, studies. One phlebotomist worked through both studies, but backup staff was provided by Roche on occasion. College students and temporary help provided urine collection, processing of specimens, and on-site coordination for the Missouri and Kansas studies. The hospital staff at St. Elizabeth Medical Center provided phlebotomy service, urine collection, specimen processing, and on-site coordination for the Granite City, Illinois, study.

All staff were trained by MRI and CDC/CEHIC staff during the preliminary trials held at the sites prior to initiation of the collection. The CDC/CEHIC laboratory protocol (Appendix A), the MRI Revised Work Plan, and supporting documentation forms (Appendix B) were used in the training. Figure 4 shows the overall collection, processing, storage, and transport scheme which was used for the Multistate Study. All handling and packaging of specimens were performed in compliance with the following documents:

- Memorandum of Instructions for Packaging and Shipping of Biomedical Materials, October 24, 1988 (supplied by ATSDR).
- 42 *CFR* Part 72—Interstate shipment of Etiologic Agents.
- MMWR August 21, 1987—Recommendations for Prevention of HIV Transmission in Health-Care Settings.
- MMWR June 24, 1988—Universal Precautions for Prevention of Transmission of HIV Virus, Hepatitis B Virus, and Other Blood-borne Pathogens in Health-Care Settings.

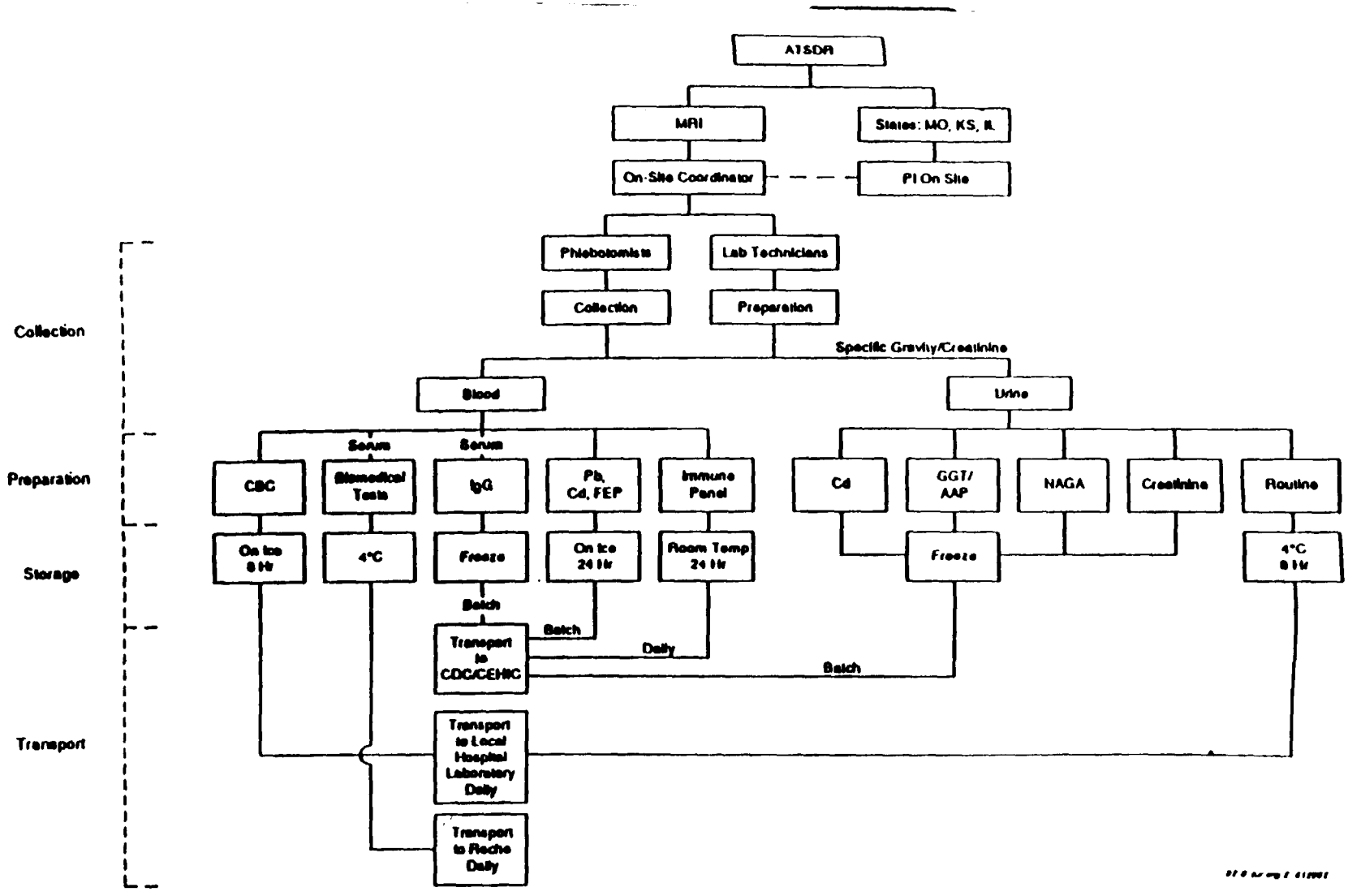


Figure 4. Collection, processing, storage, and transport of specimens.

All on-site personnel who were involved with collecting, processing, storing, or packing specimens for transport were instructed on the regulations and the correct means of handling and packaging the specimens. Copies of the above listed documents were available at each collection site. As a safety precaution, a solution of 5,000 ppm sodium hypochlorite (1:10 dilution of household bleach in water) was available at each collection site to decontaminate any spills that might have occurred.

Supervision of the staff was provided by the on-site coordinator hired by MRI, and was supported by technical advice provided by the PI on site and CDC/CEHIC staff by telephone.

4.2 COLLECTION FACILITIES

The collection facilities were selected by the States with several considerations in mind, including convenience to participants, privacy, availability of bathrooms, utilities, telephones, storage, safety, and cleanliness. Details regarding each collection facility follow.

4.2.1 Joplin, Missouri

Specimens from the study population were collected from July 16 through August 6 at the Jasper County Health Department. Blood collection and processing was performed in a partitioned area in an upstairs office. The urine specimens were collected and processed in a downstairs laundry area convenient to the restrooms and the waiting area. Since no fume hood facilities were available, urine specimens needing the addition of nitric acid were taken daily to a local university to perform that function. A room was available for storage of specimens and extra supplies. A phone was installed by the State, and copies of collection logs were made at a nearby library. No telefaxing service was available.

Collection activities were moved to the Neosho Auditorium on August 7 where specimens from the control population were collected through August 27. Blood collection and processing was performed in a stairwell area, and the urine specimens were collected and processed in a partitioned area convenient to the restrooms. No fume hood facility was available, so urine specimens needing the addition of nitric acid were taken to a nearby hospital pharmacy to perform that function. A closet was used for the storage of extra supplies. A telephone and copy machine were available for use as needed. No telefaxing service was available.

4.2.2 Galena, Kansas

The Baxter Memorial Hospital (non-operating) facility was used for the collection of specimens from both the study and control participants. Blood collection and

-ocessing were performed in the hospital pharmacy. A patient room with a restroom ..s used for urine collection and processing. A fume hood was available in the pharmacy for the nitric acid addition to selected urines. There was sufficient space in the collection areas for storage of extra supplies. A telephone and copy machine were available for use as needed. No telefaxing service was available.

4.2.3 Granite City, Illinois

Specimens from the study and control populations were collected at St. Elizabeth Medical Center. A large room, which was convenient to restrooms and the waiting area, was set up for blood and urine processing. There was sufficient space in the collection area for storage of extra supplies. A telephone, copy machine, and telefax machine were available for use as needed.

4.3 COLLECTION SUPPLIES

Collection supplies for the Multistate Study were provided by CDC/CEHIC, MRI, and the States. Table 6 gives a summary of the supplies used and by whom they were provided.

4.4 SCHEDULING PARTICIPANTS

Scheduling participants for interviews and specimen collection was performed by staff from the individual States. Scheduling was adjusted based on the number of participants, the time of the first and/or last appointment, shipping restrictions, and the CDC/CEHIC work load. Generally, the days and hours of operation for each site were as follows.

Site	Hours of Operations
Joplin, MO	M-F, varied hours
Galena, KS	M,W—3 p.m. to 8 p.m.; T,Th—11 a.m. to 6 p.m.
Granite City, IL	M-F, 8 a.m. to 8 p.m.

These hours were adjusted as necessary based on the factors mentioned above. The schedules were given by the State's PI to MRI's on-site coordinator on a daily basis.

Table 6. SUMMARY OF COLLECTION SUPPLIES PROVIDED BY CDC/CEHIC,MRI, AND THE STATES[a]

Supplier	Supplies
CDC/CEHIC	Screened collection supplies (for Pb and Cd specimens) Containers for other specimens analyzed by CDC/CEHIC. Protocol, collection logs Specimen labels Shipping containers Band-Aids™, gauze
MRI	Serum separator and transfer tubes (through Roche) Centrifuge (through Roche) Urine tubes (through local hospitals) Slides for blood smears (through local hospitals) Facility equipment Paperwork Shipping supplies Slide mailers Juice, toys, candy, Band-Aids™
Missouri	Candy, toys
Kansas	None
Illinois	Juice, toys, McDonald's® certificates

[a] Some supplies were provided jointly by more than one agency participating in the study.

4.5 STORAGE OF SPECIMENS

Specimens were stored according to the conditions identified in Tables 1 and 2 and shown in Figure 4. Prior to transport, room temperature specimens were stored at ambient temperature, refrigerated specimens in a refrigerator, and frozen specimens in a freezer. During transport, room temperature was maintained in the insulated shipping container by enclosing unfrozen cold packs, and refrigeration and freezing was maintained by enclosing frozen cold packs and dry ice, respectively, in the insulated shipping containers.

4.6 TRANSPORT OF SPECIMENS

MRI arranged the transport of all specimens to local hospitals, Roche, and CDC/CEHIC. Specimens for CBC and UA were delivered to the local hospital laboratories at least twice a day by MRI's on-site staff. The blood chemistry specimens were transported to Roche in Kansas City by their courier (Missouri and Kansas) or Flexfleet courier (Illinois). The specimens collected for the immune panel were shipped daily to CDC/CEHIC. The remaining specimens (frozen blood serum and urine) were batched and shipped to CDC/CEHIC at least once a week.

Specimens going to CDC/CEHIC were transported by Flexfleet couriers to the nearest major airport (Missouri and Kansas—Tulsa, Oklahoma; Illinois—St. Louis, Missouri), flown to Atlanta by Delta Dash, and delivered to CDC/CEHIC by Dependable Courier. Shipments were scheduled for overnight service with delivery to CDC/CEHIC by 10 a.m. The only exception was Granite City, Illinois, where Federal Express was used on Fridays, with Saturday delivery by noon.

4.7 REDRAWS

A second blood specimen was collected and transported to CDC/CEHIC for analysis for those participants found to have elevated blood lead levels. The collection and transport was arranged by MRI, using the same phlebotomists hired for the studies.

For the Joplin, Missouri study, 12 blood specimens for lead analysis were collected from participants having blood levels > 15 µg/dL. Six of the specimens were drawn during the Galena, Kansas collection in September, 1991; four were drawn at the Jasper County Health Department and two at the Joplin Health Department on September 25, 1991, and November 22, 1991, respectively. For the Galena, Kansas, study, redraws for blood lead analysis were performed on December 23, 1991, for three participants with blood lead levels of > 15 µg/dL. The collection was performed in the participants' homes.

Forty-seven redraws were performed January 6-15, 1992, at St. Elizabeth Medical Center in Granite City, Illinois for those participants with blood lead levels of > 10 µg/dL.

All of the blood lead specimens were refrigerated prior to and during shipment to CDC/CEHIC for analysis.

SECTION 5

ANALYSIS ACTIVITIES

Analysis activities performed by MRI for the Multistate Study included clinical chemistry support, data management, and Quality Assurance/Quality Control. Details about each of these analysis activities are given in this section.

5.1 CLINICAL CHEMISTRY SUPPORT

MRI was responsible for the recruitment, training, and QC oversight of the laboratories hired to perform the CBC, UA, and blood chemistry analysis. Local hospital laboratories were recruited to perform the CBC and UA, primarily due to the need to complete these analyses within 8 hrs of collection. The laboratory managers were provided lists of the tests required for the studies, and performed as the primary contact point for the MRI project leader to obtain status reports. The CBCs were performed on a Coulter Counter instrument; UAs on a Clinitek® 200.

Roche was recruited to perform the blood chemistry panel primarily due to the Kansas City location and the need to use one laboratory for all three sites of the Multistate Study. The laboratory manager was provided a list of analytes desired for the study, and a custom panel of test results was arranged by Roche. Day-to-day contact to obtain status reports on analyses was maintained with the laboratory staff. The instrument used for the blood chemistry panel was an Olympus DEMAND.

The analysis laboratories and the tests they performed are shown in Table 7. Specific components of those tests are shown in Tables 8 and 9.

5.2 DATA MANAGEMENT

Hard copy test results for individual participants were received at MRI from Roche and the local hospital laboratories. These data were compiled by MRI staff into individual files for each participant (by unique ID number), for each control, and for each replicate. The participant test results were copied and sent to a transcription service (Datatran, Kansas City, Missouri) where the data tapes were prepared using double entry procedures. The data tapes were 1600 bits per inch (bpi) in IBM format (EBCIDIC).

Table 7. LABORATORIES PROVIDING CLINICAL CHEMISTRY SUPPORT FOR THE MULTISTATE STUDY

Laboratory	Study site	Test performed
Roche Biomedical Laboratory 1706 North Corrington Avenue Kansas City, MO 64120	MO, KS, IL	Blood chemical panel Reticulocyte count[a]
Freeman Hospital 1102 West 32nd Street Joplin, MO 64804	MO, KS	Complete blood count, excluding reticulocyte count Urinalysis
St. Elizabeth Medical Center 2400 Madison Avenue Granite City, IL 62040	IL	Complete blood count, including reticulocyte count Urinalysis

[a] Performed by Roche for the MO and KS studies due to labor limitations at Freeman Hospital.

Table 8. BIOMEDICAL TESTS (SERUM)

Test	Reference range[a]		Expected coefficient of variability (%)[a]
AST (SGOT)[b]	0-6 mo	0-120 IU/L	5.41
	7-12 mo	0-110 IU/L	
	1-5 yr	0-75 IU/L	
	6-10 yr	0-60 IU/L	
	> 10 yr	0-50 IU/L	
ALT (SGPT)[c]		0-50 IU/L	8.33
GGT[d]	Male	0-65 IU/L	6.45
	Female	0-45 IU/L	
Albumin		3.5-5.5 g/dL	2.78
Total protein	Newborn	4.6-7.2 g/dL	3.23
	< 2 yr	5.7-8.2 g/dL	
	≥ 2 yr	6.0-8.5 g/dL	
Creatinine		0.5-1.5 mg/dL	4.76
BUN[e]		7-26 µg/dL	7.14
Electrolytes			
Sodium		135-148 mEq/L	1.43
Potassium		3.5-5.5 mEq/L	2.44
Chloride		94-109 mEq/L	1.98

[a] Provided by Roche Biomedical Laboratories.
[b] Aspartate Aminotransferase.
[c] Alanine Aminotransferase.
[d] Gamma-Glutamyltransferase.
[e] Blood Urea Nitrogen.

Table 9. ROUTINE BLOOD AND URINE TESTS

Specimen	Test
Blood	CBC to include: Hemoglobin and hematocrit White blood cell count and differentials[a] Red blood cell count, indices, and morphology Platelet estimate and reticulocyte count
Urine	Chemical urinalysis (routine dipstick) Microscopic urinalysis, if indicated Specific gravity

[a] Two blood slides will be prepared for manual determination of differential.

The number of records and participant ID numbers were verified at MRI prior to submission of the data tapes and corresponding bound data summary sheets for each site to ATSDR on December 20, 1991.

Slide mailers containing blood smears for manual differential were received at MRI from the local hospitals. The mailers were labeled with the patient ID number and packed numerically by site in labeled shipping boxes. The blood smear slides and bound inventories for each site were submitted to CDC/CEHIC on November 1 (Missouri) and November 26 (Kansas and Illinois).

The flow of project data at MRI is summarized in Figure 5.

5.3 QUALITY ASSURANCE/QUALITY CONTROL

Quality assurance/quality control activities performed by MRI included documentation, generation of controls, replicates and blanks, and review of test results for the routine blood and urine tests.

5.3.1 Documentation

Standard laboratory QA/QC procedures and guidelines were applied to ensure that specimen integrity was maintained throughout collection, processing, storage, and transport. These procedures and guidelines included:

- Training of personnel by MRI in the procedures incorporated into the specimen collection and shipping protocol supplied by CDC/CEHIC and the MRI work plan. A copy of the protocol and associated work plan elements was available at each collection site for reference.
- Application of replicate labels containing a unique ID number to all specimens associated with a study participant. These sequential numbers were supplied by Mr. Charles Dodson of CDC/CEHIC, and were blind to the analysis laboratories.
- Application of the unique ID number for blind replicates to the paperwork for the participant from whose specimen the replicate was prepared.
- Documentation of the collection and processing of each specimen on the collection logs.
- Documentation of the generation of quality control specimens on a daily QA/QC log.

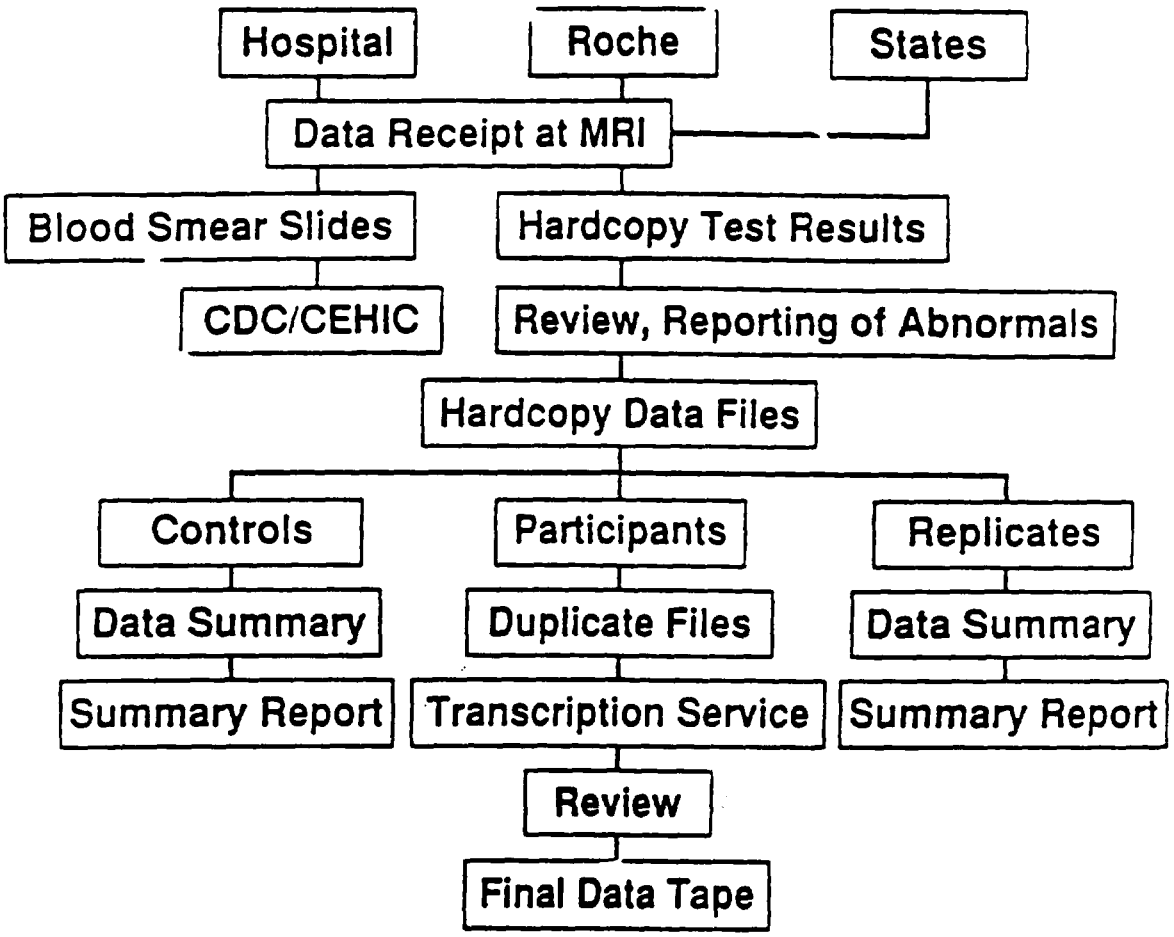


Figure 5. Flow of project data at MRI.

- Use of summary sheets to document collection of specimens and generation of QC specimens each day.

Examples of all documentation forms are given in Appendix B.

5.3.2 Controls

The on-site personnel generated quality control specimens for the biomedical tests and routine blood and urine tests. "Blind" controls were obtained from Baxter Scientific Products as follows:

- Biomedical Tests—Dade® Moni-Trol® blood chemistry controls, lyophilized, assayed serums in the normal and abnormal ranges were used. (Lot Nos. LTS-29, PTS-118, and PTS-117).

- Urinalysis—Hycor Biomedical KOVA-trol® human urine controls in the normal, high abnormal, and low abnormal ranges were used. (Lot Nos. 17192, 17920, and 30490).

- CBC—S/P® Brand Diff-Trol® 8 Plus hematology controls in the normal, high abnormal, and low abnormal ranges were used. (Lot Nos. BWT-172, BWT-173, and BWT-174).

A procedure for preparing the control specimens was written, used in training, and maintained on-site for reference. The procedure is included in Appendix D.

The blind controls were included at the rate of 15% of field specimens submitted to Roche and the local hospital laboratories for analysis.

5.3.3 Replicates

Blind replicates were prepared at the rate of 10% of field specimens and were submitted to Roche and the local hospital laboratories for analysis. Urine specimens of sufficient volume were split to provide UA replicates, and extra tubes of blood were drawn from older participants to provide CBC and blood chemistry replicates.

A procedure for preparing the replicate specimens was written, used in training, and maintained on-site for reference. The procedure is included in Appendix D.

5.3.4 Blanks

Field blanks for urine cadmium were prepared daily using water prescreened by CDC/CEHIC. The procedure for preparing the blanks is included in the CDC/CEHIC Protocol (Appendix A) and in Appendix D. The field blanks were transported with the urine cadmium specimens to CDC/CEHIC for analysis.

5.3.5 Review of Participant's Test Results

Each individual participant's test results received in hard copy at MRI from Roche and the local hospital laboratories (blood chemistry, CBC, and UA) were reviewed for abnormal results by MRI staff. Abnormal results were reported to a designated person at each site by telephone, and hard copies of the results were subsequently mailed.

Appendix E—Environmental Sample Collection

III. ENVIRONMENTAL SAMPLE COLLECTION

Preparation for the environmental sample collection begins at the field office. The environmental team will be given an assignment for the morning or the entire day. Once the assignment is received, the environmental team members will check the accuracy and completeness of the data on each environmental sample form. The Dwelling ID Number and other identifying information should be on all the environmental forms.

The environmental team will then calibrate the Paint XRF instruments (Princeton Gamma-Tech XK-2 or XK-3). Both the Princeton Gamma-Tech XK-2 and the XK-3 instruments will be used. Both instruments operate on the same principle. The newer model, the XK-3 is capable of reading only to a maximum of 10 mg Pb/sq.cm. Paint in the older housing may have higher concentrations of lead, thus, when monitoring teams visit older housing, i.e., those built before 1940, the XK-2 should be used.

After the necessary calibration of equipment, the environmental monitoring team should make certain that all equipment and supplies are ready for use (see checklist).

All members of the team should wear appropriate identification. All members should be introduced to the residents along with a short explanation of the monitoring process (see Attachment).

Exterior and interior samples will be collected. The interior samples and information to be collected is as follows:

1) Collection of tap water samples.
2) Sketching a floor plan of the residence.
3) Collection of interior surface dust samples.
4) Water system evaluation.
5) Screening for lead in painted surfaces; walls and trim, avoiding metal doors outlets, etc.
6) Collection of soil samples.

1. INTERIOR SURFACE DUST

Interior surface dust is collected by using a Hoover brush vacuum cleaner 1/3 HP, 2 Amp motor S-1083-100. At each collection a coffee filter will be fitted into the dust collection area.

The interior surface dust sample will consist of a composite of at least three sub-samples taken from the following areas in the residence:

1) An area adjacent to the main entrance.
2) A floor area in the room most-utilized by the subject child.
3) A floor area in the child's bedroom.

Additional sub-samples should be added to the composite sample, for example, from window sills which are accessible to children.

The main entry sample is collected from the floor close to the entry door. The entry mostly used by the family should be used. The identification of sample sites from the most frequently occupied room and the child's bedroom will be determined partly by the floor covering present in those rooms. If the floor is carpeted, an adequate sample can readily be collected from almos any pathway in the room. A pathway might consist of an area immediately inside of a doorway into the room or an obvious pathway from one side of the room to the other. In rooms where there is no carpeting, the most likely place to find an adequate supply of surface dust would be an area immediately adjacent to the wall. For each floor surface a one meter square area should be vacuumed.

The dust sample is collected by vacuuming the area three times. The first collection should cover the entire area completely, vacuuming back and forth in one direction. The collector should then turn 90 degrees and vacuum the entire area once again. Finally, the third collection should be taken from the original position.

As each sub-sample is collected, its location should be indicate on the floor plan which was completed earlier. Care should be taken to note the total number of the areas sampled. At the completion of the sample collection, the coffee filter will be removed from the collection device, folded and secured in a sample container. The dwelling ID number and the sample number should be written on the side of the filter paper and the outsid label of the container.

2. WATER SAMPLE COLLECTION

In older homes lead pipes and lead solder can contaminate drinking water and increase exposure to lead. In order to determine if drinking water serves as a significant source of lead the water system will be visually inspected and a first-dra sample submitted for lead and cadmium analysis.

The visual inspection of the plumbing under the kitchen sink wil serve as a surrogate for the household plumbing. The compositio of supply lines both before and after the shut-off valves will b determined to be either PVC (plastic), copper, galvanized, or lead pipe. PVC and copper are easily recognized. Galvanized pipe can be differentiated by the threaded fittings and by its hard surface, lead pipe, on the other hand, is soft and can be scored by a sharp instrument revealing s shiny, silvery surface. The supply lines after the shut-off valves are usually copper,

PVC or chrome-plated brass. The chrome-plated brass is easily recognized by its shiny metallic surface. All information regarding the plumbing supply will be recorded along with the household identification number.

Participating households will be asked to assist in collecting a first-draw water sample. The first draw is utilized to assess the amount of lead that leaches into water that stands in the pipes at least 6 to 18 hours (first thing in the morning or early evening if the water is unused during the day). Residents will be given a labelled, clean plastic bottle and instructed to collect the first draw water upon rising in the morning. The water should be taken from the cold water tape of the kitchen sink. The bottle must be filled completely with water from the first flush. Neither the faucet or fingers should touch the inside of the bottle or cap. The sample will be collected by the sampling team at a time convenient to the residents on the day that the sampling is scheduled. After picking up the sample, the pH and conductivity will be recorded followed by stabilization of the water through the addition of nitric acid. Chain-of-custody forms will be started once the sample is picked up from the residents and maintained thereafter. The person acidifying the bottle will record the time and date that the acid was added and initial the form.

3. LEAD PAINT SCREENING

The first step in the survey of lead paint in the residence is the calibration check of the instrument. For both instruments it is necessary to make calibration readings prior to taking any readings in the residence and to record those calibration readings on the paint survey form. Three separate readings will be made on the standards provided with the instruments. For calibrating the XK-2, readings should be taken with the high-lead standard, the zero-lead standard, and the 2.99 mg Pb/sq cm paint standard. The XK-3 is checked by using the zero-lead and the 1.50 mg Pb/sq cm standards. All calibration information should be added to the FORM 07 XRF Lead Paint Screening work sheet.

Two surfaces, painted woodwork and walls, in three separate rooms of the residence will be evaluated. Unpainted surfaces, such as paneling, wallpaper and unpainted woodwork will not be screened.

The three most frequently occupied rooms or areas of the residence will be screened. These areas will very likely be the living room or family room, the kitchen, and the subject child's bedroom. If these rooms are unpainted, then other alternative rooms will be selected.

In order to characterize the paint and surfaces in a given room, at least one painted wall and one painted trim in the room (door or window sill) should be screened. When screening the woodwork,

three separate readings will be taken at three different locations on the woodwork. A similar procedure will be used fo screening painted walls within a room. One reading will be tak on each of three separate wall areas, either on the same wall o on different walls within a room. If all walls are painted the same color, then the three readings can be taken from one wall. If the walls are painted different colors, then a reading from the different colored walls should be included. The mean of th three readings should be recorded for each room.

At the completion of the interior paint screening, the exterior painted surfaces should be screened. Three separate areas on t outside of the structure should be screened for lead. As with the interior screening, unpainted surfaces should not be considered. The selection of areas to be screened should be based upon: (1) apparent differences in the color and/or age o paint, (2) the apparent condition of the paint, (3) differenc in surfaces, for example, painted walls vs. trim. The location of all paint XRF readings should be noted on the sketches completed by the monitoring team or teams. All XRF readings should be recorded on the forms entitled lead paint screening.

In addition to the paint lead screening, the environmental monitors will make an evaluation of the condition of painted surfaces. This evaluation will be a rating scale of 1 to 4:

1) Intact
2) Slightly Peeling
3) Moderate Peeling
4) Extremely Deteriorated

4. **SOIL SAMPLING**

For each residence sampled, a detailed site sketch will be made that indicates the approximate size and boundaries of the lot, the position of the house, garage, other buildings, sidewalks, driveways, alleys, and streets as well as other painted structures (fences, swing sets, etc.). Obvious or reported play areas, exposed soil, rain spouts, and the general drainage patterns should also be indicated. The following information should also be noted: building type (single family, duplex, apartment building, etc.), construction (wood, brick, one-store, two-story, etc.), building condition, property condition, visibl paint debris on soil, animals present, and apparent yard use (toys, sandbox, etc.). The site sketch should include the location of the ten soil aliquots that comprise the composite sample.

Every effort should be made to identify the primary play areas used by children in the household through observation (e.g., bare soil, toys, swing sets, children at play, etc.) and information

provided by residents. One soil sample consisting of ten aliquots will be collected at each residence. The areas sampled should be selected in proportion to their size and relative degree of use or accessibility. The samples will be collected using a standard stainless steel corer and only the top one-inch of soil will be collected. Any debris or leafy matter will be removed from the top of the core while retaining soil or decomposed material. The top one-inch is selected because it is likely to have the highest concentration of metals as well as the highest exposure potential for children at play. The ten soil aliquots are combined in a stainless steel mixing bowl and composited into a single sample of uniform size that represents the play area. Obvious paint flakes will be removed prior to compositing the samples. Sampling within one foot of the foundation per story of the residence will not be done unless there is clear evidence of play activity to avoid high readings typically associated with such areas due to peeling paint. The sample corer and mixing bow will be cleaned after each sampling event using standard field decontamination methods.

The composite sample will be placed in clean eight ounce glass jars and tightly sealed to prevent sample loss and contamination. These samples will be stored in a dry, secure location at ambient temperatures until shipped to the laboratory. Chain-of-custody forms will be maintained from the time of collection. Sample numbers and household identifiers will be recorded on site sketch and description as well as the sample record sheet.

Appendix F—Field Sampling Protocols

FIELD SAMPLING PROTOCOLS

Note: In the event of inconsistencies between the following protocols and the QAPP, the protocols shall govern.

Preparation for the environment sample collection begins at the field office. The environmental team will be given an assignment for the morning or the entire day. Once the assignment is received, the environmental team members will check the accuracy and completeness of the data on each environmental sample form. The Dwelling ID Number and other identifying information should be on all the environmental forms.

The environmental team will then calibrate the Paint XRF instruments (Princeton Gamma-Tech XK-2 or XK-3). Either the Princeton Gamma-Tech XK-2 or the XK-3 instruments, or both, will be used. Both instruments operate on the same principle. The newer model, the XK-3 is capable of reading only to a maximum of 10 mg Pb/sq. cm. Paint in the older housing may have higher concentrations of lead, thus, when monitoring teams visit older housing, i.e., those built before 1940, the XK-2 should be used, if available. If the XK-2 is not available, an attempt should be made to extrapolate values greater than 10 mg Pb/sq.cm. with the XK-3.

After the necessary calibration of equipment, the environmental monitoring team should make certain that all equipment and supplies are ready for use.

All members of the team should wear appropriate identification.

Exterior and interior samples will be collected. Exterior samples to be collected are soil samples. The interior samples and information to be collected is as follows:

1) Collection of tap water samples.
2) Sketching a floor plan of the residence.
3) Collection of interior surface dust samples.
4) Screening for lead in painted surfaces; walls and trim, avoiding metal doors outlets, etc.

I. Soil Sample Collection

The Primary method of determining the lead content of the soil will be by acid digestion and graphite furnace atomic absorption spectrometry.

A. Site Description

For each location, a detailed drawing should be made that shows t boundary of the lot, the position of the main building and a other buildings such as storage sheds or garages, the position the sidewalks, driveways, and other paved areas, the position c the play areas if obvious, and the position of the areas wi exposed soil (grassy or bare), roof rain spouts and gener drainage patterns.

In addition to the diagram, briefly describe the locatio including the following information:

Type of building construction (brick, wooc etc- 1 or 2 story)
Condition of main building
Condition of property (debris, standing wate vegetation cover)
Presence and type of fence
Animals on property
Apparent use of yard (toys, sandbox, childre present)
Location of 10 soil aliquots

B. Sample Collection

Sample Collection shall be performed as outlined in the QAPP, wit the exception that all aliquots will be of equal volume and will b mixed in a stainless steel bowl prior to packaging. Assembl composite soil core segments in 8 ounce glass jars suitable fo prevention of contamination and loss of the sample. Record th sample identification number on the bag and the sample recor sheet. Store the composite soil sample at ambient temperatur until submitted to the laboratory for analysis.

Clean the corer after collecting each sample composite by reinsertion of the corer into the soil of the next sampling area.

C. Sample Handling and Storage

Seal the sample jars to prevent loss or contamination of the sample and store samples in a dry location at ambient temperature.

Record-keeping and Sample Custody: Initiate soil sample records for each location. Record sample numbers on location diagram, soil area description, and sample record sheet. Send the sample to the laboratory and release the sample to the laboratory personnel for analysis.

II. Surface Dust Collection

A. Sample Collection

A portable "dustbuster" type vacuum cleaner will be used; due to the sample size required, the Sirchee-Splittler modified dustbuster will not be used. Use a new bag for each household, to avoid cross-contamination. In order to ensure that the sample size is sufficient, either weigh the sample using a field scale or collect a large enough sample to ensure that three to five grams of dust have been collected.

B. Sample Areas

The interior surface dust sample will consist of a composite of sub-samples taken from the following areas in the residence:

Entry (E): A floor area inside the residence directly adjacent to the main entry to the residence.

Floor (F): At least 3 floor areas which should include but are not limited to a sample from a high-traffic area in the main living area and a sample from the child's bedroom. If carpet is present in the residence it shall be the first choice of sample area. If carpet is not present, a mixture of non-carpet floor areas will be sampled.

Window (W): At least three window areas (window sills and window wells), including but not limited to a window in the main living area and a window in the child's bedroom.

The main entry sample is collected from the floor close to the entry door. The entry mostly used by the family should be used. The identification of sample sites from the most frequently occupied room and the child's bedroom will be determined partly by the floor covering present in those rooms. If the floor is carpeted, a larger sample can readily be collected from almost any pathway in the room. A pathway might consist of an area immediately inside of a doorway into the room or an obvious pathway from one side of the room to the other. In rooms where there is no carpeting, the most likely place to find an adequate supply of surface dust would be an area immediately adjacent to a wall. For each floor surface, an approximately one meter square area should be vacuumed. Additional living areas (e.g. additional floor areas, around furniture, etc.) Should be vacuumed, if necessary, to obtain an adequate sample size. In no event shall dust be obtained from household areas where dust

generally collects for long periods of time, such as behi major appliances, under beds, etc.

The sample sequence should be as follows: collect t bedroom, kitchen and living room samples first. Then, colle the floor sample from the entry way. Then, collect the wind well samples. Finally, if necessary, collect the samples fr additional living areas.

C. Sketch of Residence

In order to more fully describe where samples have be collected, a top view of the residence will be made by t sampling crew. This sketch should show the primary feature of the residence, including a north arrow indicator and t relationship of the various rooms to each other. The sampli areas should also be indicated. Rooms should be labele according to their apparent function.

III. Water Sampling

Residents will be provided with clean, capped bottles a instructed to collect water on the day of schedule environmental sampling. The sampling team or its manage should give the following instructions to the resident wh will collect the sample:

The tap water sample should be taken from the cold wate faucet of the kitchen. It should be a first flush sample o water that has been standing in the pipes from 6 to 18 hours There are two options for the time a sample is taken: (1) i can be taken first thing in the morning, or (2) if all of th residents of the household have been out of the house for th entire day, it can be taken at the end of the day (i.e. dinne time). Labelled plastic bottles will be provided for the sample. The bottle should be completely filled with water. The sampling team will pick up the sample at a convenient time on the day of scheduled environmental sampling.

Before dropping off a water collection bottle, the appropriate member of the sampling team will fill out and affix the label provided. The chain of custody form will be initiated when the collectors pick up the water sample. Region V will record pH and conductivity prior to acidifing the sample.

At the end of each collection day, water samples will be acidified with nitric acid, per required protocol. After the addition of the nitric acid to the water sample, the initials of the person adding the acid to the sample and the time and date will be recorded. In no event will the nitric acid preservative be provided to the residents.

WATER SYSTEM EVALUATION

An evaluation will be made of the plumbing under the kitchen sink in order to determine the composition of water lines servicing the kitchen sink. The water supply beneath the kitchen sink generally consists of hot and cold water pipes coming from either the wall behind the sink or, occasionally, up through the floor into the cabinet beneath the sink. These supply lines generally terminate at shut-off valves beneath the sink. The supply lines continuing from the shut-off valves are generally of different material than the supply lines going to the shut-off valves.

Supply lines in residential construction can be copper, galvanized, PVC, or lead pipe. PVC pipe is easily identified because of its plastic composition. Copper pipe can be identified by scraping the surface corrosion from the pipe to reveal the bright copper color. Galvanized pipe can be recognized by the threaded fittings if present and visible or by the hard surface of the pipe. Lead pipe can be recognized by the softness of the material. It is easily bent into shape and can be scratched with a knife blade or other hard tool. When scratched, the exposed surface is silvery in color.

The supply lines running from the shut-off valves to the sink generally are copper, chrome-plated brass or PVC. The PVC is easily recognized because of its plastic composition. Chrome-plated brass is also easily recognized because of the shiny surface. Copper can be identified by scratching the surface to reveal the copper color. Identifying the composition of the plumbing system beneath the sink completes the evaluation of the plumbing system. All information should be recorded.

IV. Paint Sampling Protocol Using an XRF Analyzer

A. Background and Selection of Surfaces

The concentration of lead in paint will be determined by using an X-ray fluorescence analyzer. Two types of instruments may be used, the XK-2 or the XK-3, both manufactured by Princeton Gamma-Tech, Inc. The XK-3 with a range of 0-10 mg of Pb per cm^2 will be the primary instrument used. If available the XK-2 will be a backup and also used in the event a reading on the XK-3 exceeds 10 mg/sq cm^2.

In each residence two surfaces, a painted woodwork and a painted walls in each of three rooms or areas most frequently occupied by the subject child will be evaluated (e.g. child's bedroom, kitchen, living room). One reading will be taken at

three different locations on each type of surface. identity of the rooms and the Pb found in the paint will recorded. In addition, a copy of a floor plan of the

residence will be available to the technician and on which sample location will be noted. All unpainted surfaces, s as paneling, wallpaper, and unpainted woodwork will not tested. In the event a room-selected is unpainted alternate room will be selected and this information record

In order to characterize the paint and surfaces in a gi room at least one painted wall and one painted trim in room (door or window sill) should be screened. When scr the woodwork, three separate readings will be taken at th different locations on the woodwork. A similar procedure w be used for screening painted walls within a room. reading will be taken on each of three separate wall are either on the same wall or on different walls within a ro If all walls are painted the same color, then the th readings can be taken from one wall. If the walls are pain different colors, then a reading from the different colo walls should be included. Whenever changing areas locations, one reading should be taken to clear the mach prior to taking the actual reading to be recorded. arithmetic mean of the eighteen readings should be recorded the reading for the house. Each individual reading will a be recorded to provide data for future follow-up actions, necessary.

XRF readings will be taken by placing the instrument on t designated surface and opening the shutter. (More accura readings can be obtained from flat surfaces so curved surfac will be avoided). Once the shutter is opened the lead conte of the paint will appear as a visual numerical display on t instrument. The operator will read the number for the oth team member to record. This will be repeated back to t operator.

In addition to the paint lead screening, the environment monitors will make an evaluation of the condition of paint surfaces. This evaluation will be a rating scale of 1 to

1) Intact
2) Slightly Peeling
3) Moderate Peeling
4) Extremely Deteriorated

B. Operation of the XRF Analyzer to Determine the Concentrati of Lead

At the start of each day the performance of the X instruments are evaluated using standard procedures. Prior

taking readings at the residence, calibration checks will occur using reference material prepared by the Department of Housing and Urban Development. After the designated areas in the home have been sampled and before the team is ready to leave, the instrument's calibration will once again be checked. All calibration information should be added to the FORM 07 XRF Lead Paint Screening work sheet, if available, or equivalent form.

Following is the Operating Procedure for the XK-3 unit:

1. Remove the battery pack, coiled cable, and XK-3 unit from the carrying case.

2. Connect the battery pack to the XK-3 unit, using the coiled cable.

3. Locate the LOCK SWITCH underneath the handle toward the rear of the unit and push it forward. A red light over the display window will now glow to indicate that the instrument is ready to perform its analysis as soon as the shutter is opened.

4. Depress the RED RESET button on the back plate of the unit, just above the coiled cable connection, and hold for 8-10 seconds.

5. Grasping the wooden handle, position the face-plate of the instrument against the surface to be measured and push down firmly and evenly on the handle to spring the shutter open. The red light over the window will now blink to indicate that the shutter is open and that the measurement is taking place. As soon as the shutter opens, the previous read-out in the window vanishes, leaving the window blank except for a single decimal point.

6. Keep the handle firmly depressed until the new read-out appears.

7. When the new read-out appears, release pressure on the handle. The display window retains read-out until the handle is pushed down again to begin another measurement.

8. Push the lock switch back to the lock position when readings are completed.

Appendix G—EPA Memorandum Entitled "SAS Requests for the NL Industries Taracorp Lead Smelter Site, Granite City, IL"

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION V

DATE: 24 OCTOBER 1991

SUBJECT: SAS REQUESTS FOR THE NL INDUSTRIES TARACORP LEAD SMELT SITE, GRANITE CITY, IL K7

FROM: JAN PELS, RSCC

TO: ELENOR MC LEAN, SMO SAS COORDINATOR

The sampler is E&E. The activity does not fit into a standard category; it is a Superfund non-enforcement ATSDR Multi-State Lead Exposure Study.

The samples have already been collected and will be shipped within one week of award of the SAS contracts. While the number of samples is large, the analysis is for two metals only. A single lab for each matrix type is preferred (one lab for the waters and one lab for the soils). Please keep me informed if during the solicitation this requirement becomes a problem.

There will be a total of 414 soil samples and 446 water samples for lead and chromium analysis using the two attached SAS requests. For each matrix, we will require a 14 day turnaround on approximately 40 samples each. These priority samples will be identified up front and will be sent as the first shipment. All remaining samples will then be shipped within a few days. Data for the remaining samples will be due within 42 days of VTSR. This will allow the lab to perform the sample analyses at a rate of approximately 100 samples per week for the remaining 4 weeks after submission of the priority sample data.

Note that for the water samples, the lab is required to FAX the RSCC or ship out via overnight mail the results for the first 10 samples. The Region will review the data within 2-3 days of receipt and will contact SMO to confirm that the analyses can proceed according to the specifications in Section 8 of the SAS with a lesser rate of analytical spikes.

Please call if you have any questions.

Thank you.

Approved For Schedule
10/21/91 JH

.S. Environmental Protection Agency
LP Sample Management Office
.O. Box 818, Alexandria, Virginia 22313
HONE: 703/557-2490 or FTS/557-2490

SAS number

SPECIAL ANALYTICAL SERVICES

Client Request

☐ Regional Transmittal ☐ Telephone Request

A. EPA Region/Client: Region V/ARCS, E & E
B. RSCC Representative: Jan Pels
C. Telephone Number: (312) 353-2720
D. Date of Request: 10/8/91
E. Site Name: NL Industries, TaraCorp Lead Smelt Site, Granite City, I

Please provide below a description of your request for Special Analytical Services u Contract Laboratory Program. In order to most efficiently obtain laboratory capabili request, please address the following considerations, if applicable. Incomplete or a information may result in delay in the processing of your request. Please continue r additional sheets, or attach supplementary information as needed.

1. General description of analytical service requested: Analysis of cadmium and le Graphite Furnace Atomic Absorption of "first-draw" drinking water from private r

2. Definition and number of work units involved (specify whether whole samples or fr whether organics or inorganics; whether aqueous or soil and sediments; and whethe medium, or high concentration): 390 investigative samples, 37 field duplicates. blanks. Samples and blanks will be acidified with 5.0 mL of 50% HNO_3 per liter and will generally not be digested prior to analysis because of insignificant su solids content. Samples will be from a single public water supply system (whose a river water) having low to moderate total dissolved solids of 250 to 400 mg/L tap. SMO and Region V may visit the laboratory during initial analyses to audit analytical specifications, to provide corrective actions, and to minimize proble associated with data review.

Purpose of analysis (specify whether Superfund Remedial or Enforcement, RCRA, NPDES etc.):

Superfund [illegible]

Estimated date(s) of collection: September 4 - October 4, 1991

Estimate date(s) and method of shipment: ASAP after lab selection; Federal Express

Number of days analysis and data required after laboratory receipt of samples:

21 days after receipt of last sample in each SDG (20 samples) (21 days is negotiable for a SDG within the context of the entire project).

Analytical protocol required (attach copy if other than a protocol currently used in this program):

Samples and blanks will be acidified with 5.0 mL of 50% HNO_3 per liter to pH <2. Sample will not be digested prior to analysis because of insignificant suspended solids content from a public water supply tap. If suspended solids are noted, they will be so indicated on traffic report, and lab will digest samples (per SOW 3/90) prior to analysis. Lab will also shake samples prior to any analysis. Lab will also digest samples at its discretion if suspended solids are noted (for first 140 samples collected, observations are that none should require digestion).

All standards, blanks, and initial and continuing calibration verification standards will be matrixed-matched to the sample preservation (5.0 mL of 50% HNO_3 per liter).

Instrumental analysis will be Method 213.2 CLP-M* (Atomic Absorption, Furnace Technique) for Cd and Method 239.0 CLP-M* (Atomic Absorption, Furnace Technique) for Pb. Calibration range of each GFAA should cover the range of 0.1 or 0.2 to 2 or 4 ug/L for Cd Cd and 1 or 2 to 25 or 40 ug/L for Pb.

Lab must supply its instrument operating procedures (including temperature program Pb and Cd) with bids to SMO.

7. Analytical protocol required (attach copy if other than a protocol currently used in this program) (Cont.):

Instrumental performance must be such that Method of Standard Additions (MSA) necessary and analytical spikes of 85 - 115% recovery are obtained without signif. sample dilution (double injections required) using assumptions that undigested sa of uniform matrix of low to moderate dissolved solids, sample preservation is uni cadmium will rarely be detected, if at all, and most lead contents will range fro to 10 ug/L.

It is mandatory that required Instrument Detection Limit (IDL) for Pb not be g than 2 ug/L, and not be increased due to sample dilution (except for any digested exceptional samples encountered).

Analysis operations for Cd and Pb by GFAA will be by CLP SOW 3/90, modified pe Technical Instruction in Item #8 to allow for quantitation from calibration curve

Double injections are required for all standards, blanks, samples, and analyti spikes.

Analysis procedures for samples requiring digestion will strictly adhere to an utilize required SOW GFAA "decision tree". Standards, blanks, samples, etc. must matrix matched.

8. Special technical instructions (if outside protocol requirements, specify compound names, CAS numbers, detection limits, etc.): For each GFAA instrument, the first samples tested (double injections) will use the analytical spiking "decision tree" presented in SOW 3/90 to verify analysis procedures for all of the samples to be Analytical spikes can be larger than two times lead concentration but are to be wi usable calibration range of the instrument. Initial results are to be forwarded t and Region V by fax and/or overnight mail for verification within 7 days of recei

Two to three days after receipt of initial results, Region V will contact SMO t

Special technical instructions (if outside protocol requirements, specify compound names, CAS numbers, detection limits, etc.) (Cont.):

that the remaining samples will be analyzed using analytical spikes at a lesser frequency as described here.

After verification it is expected that the samples of uniform matrix can be tested without an analytical spike for each sample. Analytical spikes are to be performed at a frequency of 1 in 5 or 1 in 10, with recoveries of 85 to 115%. If analytical spikes are outside of this range, all intervening samples are to be retested, or MSA is to be followed. Sample dilution is allowed for cadmium to achieve desired accuracy and still meet the required detection limit. Sample dilution is not allowed for lead to meet required accuracy. The decision of whether to use 1 in 10 or 1 in 5 analytical spikes will be made by the laboratory based on consequences for reanalysis and instrument instability.

QC requirements will be mandatory. Data are not to be qualified by the lab for spike/dup. problems (except for unusual samples) without prior approval of SMO and Region V.

Analytical results required (if known, specify format for data sheets, QA/QC reports, Chain-of-Custody documentation, etc.). If not completed, format of results will be left to program discretion.

SOW 3/90 deliverables will be modified to allow for quantitation directly from the calibration curve. Any samples digested will follow SOW 3/90 and will require full GFAA "decision tree". Initial 10 to 20 Cd and Pb analysis will be performed according to full GFAA "decision tree" of SOW 3/90 and will be provided to SMO and Region V for review and acceptance of subsequent scheme for GFAA analyses. These initial analyses can be provided by fax or overnight mail for review, in order to minimize the amount of qualified data, with mandatory QC requirements for waters of uniform matrix.

IDLs are to be provided for each GFAA instrument (per SOW 3/90 protocols) and are to be less than 0.5 ug/L for cadmium and less than or equal to 2 ug/L for lead. All values greater than or equal to IDL are to be reported.

...additional sheets or attach supplementary information, as needed):

11. Name of sampling/shipping contact: Cathy Kouris, E & E

Phone: (312) 663-9415

12. DATA REQUIREMENTS

Parameter	Detection Limit	Precision Desired (± % or Conc.)
Cadmium	0.3 ug/L or less. Report concentra-down to specific IDL used.	±10% difference in duplicate results for concentrations greater than 2 ug/L or ±0.2 ug/L for Cd concentrations less than 2 ug/L.
Lead	2 ug/L - Report concentrations down to specific IDL used.	± 10% difference in duplicate results for Pb concentrations greater than 20 ug/L and ± 2 ug/L for Pb concentrations less than 20 ug/L.

II. QC REQUIREMENTS

Audits Required	Frequency of Audits	Limits (Percent or Concentration)
1. Calibration Blanks	Per SOW 3/90	< 2 ug/L Pb < 0.25 ug/L Cd
2. Calibration Verification (initial and continuing)	Per SOW 3/90	90-110% Recovery
3. Analytical Spikes (concentration at discretion of lab).	1 in 5 or 1 in 10 (discretion of lab but must do at least 1 in 10)	85-115% Recovery (mandatory re-analysis or MSA is necessary). if limits are exceeded.

. QC REQUIREMENTS (CONT.)

Audits Required	Frequency of Audits	Limits (Percent or Concentration)
. Field Blanks Note: Field personnel will clearly identify the field blanks.		If > 2 ug/L Pb or >0.5 ug/L Cd, contact SMO immediately for further instructions.
5. Lab Duplicates	1 in 10	±10% or ±0.3 ug/L for Cd or ±2 ug/L for Pb (mandatory reanalysis is necessary, if limits exceeded.

:. QC REQUIREMENTS (CONT.)

Audits Required	Frequency of Audits	Limits (Percent or Concentration)
. Digested samples	SOW 3/90 GFAA protocols for both Cd and Pb	See SOW 3/90

Note: No prep blanks and matrix spikes are necessary for undigested samples.

III. ACTION REQUIRED IF LIMITS ARE EXCEEDED

Please return this request to the Sample Management Office as soon as possible to expedite processing of your request for Special Analytical Services. Should you have any questions or need any assistance, please call the Sample Management Office.

7360:1

Received For Scheduling
10/2-91 &

U.S. Environmental Protection Agency
CLP Sample Management Office
P.O. Box 818, Alexandria, Virginia 22313
PHONE: 703/557-2490 or FTS/557-2490

SAS number

SPECIAL ANALYTICAL SERVICES
Client Request

☐ Regional Transmittal ☐ Telephone Request

A. EPA Region/Client: Region V/ARCS, E & E
B. RSCC Representative: Jan Pels
C. Telephone Number: (312) 353-2720
D. Date of Request: 10/8/91
E. Site Name: NL Industries, TaraCorp Lead Smelt Site, Granite City,

Please provide below a description of your request for Special Analytical Services Contract Laboratory Program. In order to most efficiently obtain laboratory capabi request, please address the following considerations, if applicable. Incomplete or information may result in delay in the processing of your request. Please continue additional sheets, or attach supplementary information as needed.

1. General description of analytical service requested: Analysis of cadmium and emission spectroscopy of soils from private residences. Analysis aliquots wil from 103-105° C residue from percent solids determination. Results will be re dry weight basis (% solids values will be reported).

2. Definition and number of work units involved (specify whether whole samples or whether organics or inorganics; whether aqueous or soil and sediments; and whe medium, or high concentration): 375 investigative samples and 39 field dupli Samples are generally dry soils that are composited in the field from several samples. One 8-oz. glass jar will be provided for each sample. Certain QC a SOW 7/88 or ILM01 will be mandatory, not advisory. To improve precision of a any heterogeneous sample after % solids test will be homogenized using SPEX 8 Mill, or equivalent. SMO and Region V may visit the laboratory during initia audit SAS analytical specifications, to provide corrective actions, and to mi problems associated with subsequent data reviews.

Purpose of analysis (specify whether Superfund (Remedial or Enforcement), RCRA, NPDES, etc.)

Superfund - RSCC Multi-State Lead Exposure Study

Estimated date(s) of collection: September 4 - October 4, 1991

Estimated date of and method of shipment: ASAP after lab selection; Federal Express

Number of days analysis and data required after laboratory receipt of samples:

21 days after receipt of last sample in each SDG of 20 samples (21 days is negotiable for a SDG within the context of the entire project).

Analytical protocol required (attach copy if other than a protocol currently used in this program):

Most samples are expected to be uniform soils of low moisture content after compositing. A ten gram sample aliquot will be selected for % solids test (103-105° C) and residue will be used for sample analysis. Residue will be broken up into free-flowing powder so that representative 1g sample aliquots can be selected, and the unused portion must be archived. Any heterogeneous soil samples will be homogenized prior to analysis, using an air-dried aliquot, and a SPEX 8000 Mixer Mill (or equivalent). Laboratory has discretion to homogenize all soils prior to analysis. Samples will be digested using SOW 7/88 or ILM01. ICP calibration standards and sample digests will be matrix-matched (1g. of soil will be digested for 200 mL of final solution) as to acid contents. If microwave digestion of ILM01 SOW is used, standards, QC solutions, and digests must be matrix matched as to nitric acid concentration.

Sample digests will be tested for Cd and Pb using ICP emission spectroscopy of SOW 7/8 or ILM01, including solid Lab Control Standard, with extra QC criteria listed below. All elements necessary for interelemental corrections and dissolved solids interferences will be measured and reported in raw data. Only Cd and Pb will be reported on Form I for each soil sample.

Provide the following information to SMO with bids:

8. Special technical instructions (if outside protocol requirements, specify compound names, CAS numbers, detection limits, etc.): Prior to any sample shipment, laboratory will provide to SMO and Region V for each ICP instrument to be used: 1) Instrument Detection Limits; 2) Instrument Linear Ranges for Cd, Pb, and any major elements used for interelemental corrections (Al, Ca, Fe, etc.); 3) primary analytical wavelengths used for Cd, Pb, and interelemental correction elements; and 4) Interelemental Correction Factors and background subtraction points for Cd and Pb. These items of information will be reviewed for approval prior to selection of laboratory.

9. Analytical results required (if known, specify format for data sheets, CA/CC reports, Chain-of-Custody documentation, etc.). If not completed, format of results will be left to program discretion.

Data deliverables will be in accordance with ILM01, including notations for any samples requiring sample homogenization prior to analysis. A floppy disc deliverable is not required. Note: A dried sample aliquot will be used for the analysis. Therefore, a % moisture value must be reported on the Form I, the final analyte concentrations be based on the dry aliquot weight and should not be corrected for % moisture.

10. Other (use additional sheets or attach supplementary information, as needed):

11. Name of sampling/shipping contact: Cathy Kouris, E & E

Phone: (312) 663-9415

12. DATA REQUIREMENTS

Parameter	Detection Limit	Precision Desired (± % or Conc.)
Cd	5 ug/L in Digest or 1.0 mg/kg in soil (for 0% moisture)	± 20% RPD for difference in duplicate results greater than 10 mg/kg or ± 2 mg/kg for results less than 10 mg/kg

Appendix H—Quality Assurance Project Plan

Table of Contents

Attachments: Region VII SOPs/Documents Referenced in this document:

1330.2A, 1610.1B, 2110.2A, 2130.2A, 2130.3A, 2130.4A 2130.8A, 2322.1A, 2334.10A, 3121.6A, 3121.8A, 3121.11A, 3121.13A, SG04A, QAPJP for XRF

I. Project Description

Granite City, Illinois is the location of a former secondary lead smelting facility. Metal refining, fabricating, and associated metal processing activities have been conducted at the site since 1903. From 1903 to 1983, secondary smelting occurred on-site. Secondary smelting facilities included a blast furnace, a rotary furnace, several lead melting kettles, a battery breaking operation, a natural gas-fired boiler, several baghouses, cyclones and an afterburner. Most (85 percent) of the air samples taken from Granite City between 1978 and 1981, as part of IEPAs newly instituted air quality testing for lead, showed lead levels higher than levels the federal government considers safe. Metallic pollutants, which have been dispersed throughout the environment in Granite City and the surrounding areas, have heavily contaminated soil in the study area. It is likely that uptake of metallic pollutants by plants and animals, including humans, has occurred. The Agency for Toxic Substances and Disease Registry (ATSDR) has provided funding to the State of Illinois to conduct a comprehensive blood lead/urinary cadmium study on a representative number and distribution of eligible residents nearby the site. The study will include the collection of samples from potential study will include the collection of samples from potential environmental sources of lead and cadmium: soil, house dust, drinking water and indoor paint, from all participant households.

The objectives of the overall study are defined in the ATSDR study protocol (Draft; Summer, 1991; pages 8 and 9). Of the seven objectives listed, the objectives to which EPA participation will contribute are:

> "To determine the level of environmental lead and cadmium contamination found in target areas and compare them with levels of contamination found in comparable non-target areas."
>
> "To determine the extent to which environmental, behavioral, occupational, and socio-economic factors influence exposure to lead and cadmium in target and non-target populations."
>
> "To determine the extent to which exposure has occurred in populations living in areas with both mining and industrial emissions compared to populations living in areas with industrial emission only."

In order to contribute to meeting these goals, EPA will collect environmental samples at the residences of selected study

participants, as discussed in section IV.A.2, below. Of special interest in the study will be households with children between 6 and 71 months of age.

The specific objectives of EPA participation in the study will be:

1. Collection of representative samples of house dust, drinking water, and play area soil, and in-situ analysis of paint by XRF for Pb (Paint is not considered a major exposure route for Cd), from a randomly selected subset of study participant residences.

2. Provision of data to ATSDR for determination of the probability that a statistically significant relationship, if any, exists between the environmental lead levels in the four sampled media and the human exposure data.

Environmental sampling in this study will be performed by the U.S. EPA Region V contractor, Ecology and Environment (E&E). Environmental samples will be sent by E&E to a CLP lab for analysis. E&E will report analytical results to U.S. EPA Region V. This document describes the procedures and activities which will be applied to such samples.

II. Project Organization and Responsibilities

A. Pat Van Leeuwen, toxicologist, WMD/OSF/TSU, will have the responsibility for maintaining overall communication with ATSDR and the Illinois Department of Public Health and for providing input on questions having toxicological aspects.

Brad Bradley, Remedial Project Manager, WMD/OSF/IL/IN Section, will be the EPA contact to E&E, which will perform project sampling, and will provide input on questions having technical aspects.

B. The Illinois Department of Public Health (IDPH) shall, through designated representatives, interface with Mr. Bradley to provide listing of names, addresses, and telephone numbers of all households where environmental sampling is to occur. Identification and notification of households with children exhibiting elevated blood lead or urinary cadmium levels shall be the responsibility of IDPH.

C. As noted above, environmental sampling in this study will be performed by the USEPA's contractor, Ecology and Environment. The

contractor, in accepting the assignment to support this Study, agrees to perform sampling activities as outlined in this Plan and in conformance with applicable Region V CLP protocol the attached Region VII Standard Operating Procedures (SOPs), and other guidance which may be provided by EPA for performance of Study-related activities.

D. Sample receipt, storage, handling, and custody within the laboratory will be the responsibility of the selected CLP laboratory.

E The selected CLP laboratory will receive and analyze the environmental samples and report analytical results to Region V representatives, following procedures outlined in this Plan and applicable Region VII SOPs referenced below.

F. Final data review and validation will be the responsibility of E&E, after normal review of the data during and after analysis by the analyst, supervisor, and data review or QA/QC personnel at the CLP lab.

G. Transmittal of reviewed and validated data on disk to U.S. EPA Region V will be the responsibility of E&E.

H. Transmittal of final data in a brief report to U.S. EPA Region V will be the responsibility of E&E.

I. Brad Bradley will be responsible for the dissemination of applicable environmental data to the appropriate entities in the State of Illinois, for responding to questions from the State, and for addressing public questions relating to the study from the Federal perspective.

J. ATSDR will assume final Federal responsibility for the Study data because of the greater protection of individual privacy afforded ATSDR data bases; EPA final data is subject to FOIA request actions. ATSDR will perform statistical review of the environmental data vis-à-vis human exposure data. All study data shall be made available to EPA upon request, for purposes such as evaluating the Pb uptake/biokinetic model.

K. Program and field sampling QA/QC oversight will be the responsibility of E&E.

III. Data Quality Objectives

A. The data quality objectives (DQS) for this project are to generate data that are of sufficient quality to enable the objectives of this project to be met. The sampling and analytical methods selected for this project (SOPs are referenced elsewhere) are consistent with these objectives in terms of accuracy, percision, and representativeness. Of the quantitative DQO components, the quantity of data, or completeness, is typically based on assumptions regarding the statistical variability of the study population to be sampled. For this project there are insufficient data available to make these assumptions with any degree of confidence.

B. An additional completeness goal for the laboratory will be the generation of useable analytical data for at least 95% of the samples received in acceptable condition. This means that out of the total amount of data that might potentially be generated for all samples analyzed, no more than 5% of the data will be unusable due to failure to meet analytical accuracy, precision, or detection limit goals stated in the referenced SOPs, caused by analytical problems such as matrix interferences, or problem such as laboratory accidents, holding times or preservation violations, etc.

C. To minimize variability in the data reported as part of the Study, it is incumbent upon field samplers and their supervisors to become familiar with all sampling guidelines and procedures included herein or referenced, so as to ensure that the data reported from this Study will represent the overall environment form which the analyzed samples are taken. Any sub-sampling procedures performed in the laboratory will be done in accordance with applicable sample handling SOPs.

D. To insure the comparability of data produced for this Study to that produced under other plans or studies, EPA accepted sampling and analytical methods, as documented in SOPs referenced herein, will be used whenever possible. All SOPs referenced are available in the ENSV Operations and QA Manual, USEPA Region VII, ENSV Division, 25 Funston Road, Kansas City, KS 66115.

E. Method detection limits are dependent upon the specific properties of, and interferences present in, a given sample, and so may not always be achieved. Detection limit goals ar to be one tenth the action levels specified in the table below for both metals in various media.

These detection limits will permit evaluation of field sample data against the following limits, so as to determine whether the samples are above background levels with a 95% confidence level.

Sample Medium	Action Level Lead	Cadmium
House Dust	500 ug/g	136 ug/g
Paint	0.7 mg/sq.cm.	N/A
Drinking Water	15 ug/L	5 ug/L
Play Area Soil	500 ug/g	136 ug/g

Note the detection limits of one-tenth the action levels noted may not be achieved if the minimum sample amounts discussed in Section IV, Sampling Protocols, are not collected. Also, available analytical methods may not permit analysis of Cd in water at concentration as low as 0.5 ug/L. A detection limit of 2.0 ug/L will be acceptable for lead in water.

IV. Sampling Protocols

A. Environmental Sampling Design Considerations

1. Selection of Residences to be Sampled:

   a. In order to meet the Study goals outlined above, EPA Region V will collect environmental samples: soil, house dust, drinking water and paint, from all households in the Study area at which biological sampling is scheduled. In order to identify high biomedical metal levels, an action level of 10 ug/dL of Pb in blood and/or 8 ug/L Cd in urine will be used.

   b. Environmental sampling will be conducted at all households where biomedical testing occurred. The names, address, and telephone numbers of residences to be sampled shall be forwarded to EPA by IDPH as soon as practicable. EPA plans to perform environmental sampling in on sampling event which is scheduled to begin the first week of September, and will last approximately four weeks.

c. Residential environmental sampling will be conducted as summarized in the table below:

Sampling Area	Total Households in study	# of Sampled Households
Granite City and the adjacent areas of Madison and Venice, IL	250	100% of homes
Control area - Pontoon Beach	250	100% of homes

B. **Pre-Sampling Verification Interview and Briefing**

Prior to sampling, the IDPH will contact the study households to obtain access agreements for environmental sampling. IDPH shall then forward the names, addresses, and telephone numbers of households to be sampled to the EPA, which shall forward appropriate information to E&E.

If possible, E&E shall confirm sampling plans with a given household within one week of the scheduled sampling event. Upon arrival, the E&E sampling teams will briefly speak with the homeowner or other adult resident about the purpose and nature of the visit, and provide them with information written by ATSDR, to include telephone contacts for additional information.

If for some reason a household cannot be sampled (e.g. one is home), an attempt to reschedule sampling will be made.

C. **Sample Collection, Documentation, and Handling**

1. **Sampling Number System:** All samples will be assigned a unique identification number according to Region V CLP protocol. EPA will report data to ATSDR using such identification numbers, along with sufficient documentation for ATSDR to correlate the data with biomedical metal levels in study participants, and any other data collected by ATSDR or IDPH. All analyses shall be performed "blind" by the CLP laboratory staff; correlation or analytical data with site location information shall be performed after the analytical results are complete, as part of generating the final report to be forwarded to other project participant organizations.

2. Sample Containers: Sample containers and associated supplie will be obtained by E&E and prepared and utilized per SO 2130.4A, with the exception that one liter poly bottles wil be used for the collection of water samples. In the even sample container and preservation information in this QAPJ contradicts any information in the attached SOP, this documen shall have precedence.

3. Sample Collection Procedures:

Note: See the attached Appendix A, which shall supercede th language below in the event of any inconsistencies.

a. Drinking Water samples will be collected in accordance wit SOP 2334.10A, wi : the following exception: all samples c drinking water will be first-draw samples, as specified in th EPA's Final Rule for Lead and Copper in Drinking Wate: Federal Register, June 7, 1991. These samples may b collected by the residents in sample containers wit appropriate preservatives, supplied by E&E in advance, a: picked up at the time of the dust, soil and paint sampling Alternatively, E&E may chose to send a sampler first thing the morning to all residences to be environmentally sample that day to draw the samples, after pre-arranging with th residents so that the water is not turned on prior t sampling. Either method is acceptable, but the method chose must be applied consistently to all residences sampled durir the project, and the choice of method must be documented i writing by E&E in the final project report.

One field blank (deionized water) will be submitted blind fc laboratory analysis at a frequency of one in each set c twenty field samples.

b. Indoor House Dust: field sampling personnel will collec residential dust samples form primary play areas (areas mos likely to impact on a child's hands or result in ingestic during indoor activity). A minimum of three areas should b sampled: ~~at the main entrances~~ to the household, and t additional areas most likely to be use by children in th household for play areas. Additional areas for sampling m include secondary entrances to the home (back or side doors dust on window sills, furniture, and carpet in additional pl areas or areas of frequent activity by the children. Bedroo Kitchen, and living room floor samples will be collect first, followed by floor samples frc the entry way. Finall samples from window wells will be collected.

Once the individual sampling areas are determined, they should be noted on the sampling sheets, including the total area sampled for the household. One composite sample of dust will be taken and analyzed per household.

Vacuum equipment to be used will be equipped with a pre-weighed glass fiber filter (the weight of each filter will be noted in indelible ink on its zip-lock by the laboratory prior to shipment to the field) to trap the dust. The filter will be removed between residences and placed in a zip-lock bag for laboratory analysis. Alternatively, a modified portable "dustbuster" type vacuum cleaner may be used (Sirchee-Splittler method), with the dust removed after sampling each residence and placed in a zip-lock bag. The compressed air between residences. Other necessary sampling equipment are zip-lock baggies containing pre-weighed filters with the weight noted on the bag in indelible ink, and a cylinder of compressed air to decontaminate sampling equipment.

c. Indoor Paint: Indoor paint shall be analyzed in-situ by a portable X-Ray Fluorescence (XRF) instrument, operated per manufacturer's instructions. Measurements will typically be made in play areas below three feet in elevation from the floor, indoor walls, door frames, window sills, and banisters, with special attention given to areas indicating peeling or chipped paint, or evidence of chewing on the surface by the resident children. A minimum of five locations will be measured and recorded on the field sheets. The condition of each painted surface sample will be noted on the field sheets by the instrument operator. The mean of the several individual readings will be reported as the paint lead value for the residence. Additional information is provided in the attached Region VII QAPJP for XRF.

d. Play Area Soil: Field sampling personnel will identify play areas on the property used by children in the household through information available from the previous household survey (area census), pre-sampling questions of the residents, and visible signs of use (e.g. bare soil under a swing set). For each site a site sketch will be made on the sampling form indicating the position of the main building and any other buildings such as sheds or garages, paved areas, and play areas.

A representative number of such location(s), comprising not less than ten aliquots, will be proportionally sampled based on their relative areas and apparent degree of use; these are then composited to produce the one sample forwarded to the lab representing the entire play area. Exact locations to be sampled at a given residence will be chosen per the professional judgement of the sampling team leader, and will be fully documented on the field sheets. A corer shall be used to sample the top one inch of soil. Debris and leafy vegetation will be removed from the top of the core, but not soil or decomposed matter; this part of the soil sample is likely to be the highest in metal contamination. Samples will not be taken from locations within one foot of the house foundation per story of the residence unless there is clear indication such areas are in use as play areas, as chipped or peeling exterior paint may produce a typically high readings in such locations.

4. Field Sample Documentation:

a. Field Sheets: Field sheets per SOP 2130.3A shall be used to document locations and times of sampling, as well as all other appropriate details. In particular, sketches should be made of the locations sampled, especially dust and soil samples taken in the play areas, as noted above. E&E shall retain field sheets until instructed otherwise by EPA.

b. Sample Chain of Custody: Sample chain-of-custody forms will be prepared per SOP 2130.2A.

D. **Sample Delivery**

All samples to be analyzed under this play will be delivered to the CLP Laboratory in accordance with applicable SOP, including SOP SG04.0A and 2130.3A. Each set of samples will be delivered along with appropriate field documentation, Chain-of-Custody forms, and "Analytical Services Request Form(s)".

V. Sample Receipt and Custody

A. Immediately upon receipt of Study samples the CLP personnel will unpack and inspect the shipment, sign the Chain of Custody form, initiate appropriate internal tracking records, and store the samples in a secure area. If inspection of the shipment causes wither the integrity or condition of the samples to be questioned (e.g. samples not cooled, broken containers, etc.), such observations will be noted on the

Chain of Custody Record and brought to the attention of the Chief, CLP lab.

B. The CLP personnel or other appropriate personnel will be responsible for the custody, storage, handling, and disposal of all samples received for analysis under this plan in accordance with SOP 2130.8A.

1. Prior to analysis all non-aqueous samples received for analysis under this plan will be stored at ambient temperature. All aqueous samples will be stored per CLP protocols.

2. Samples will be analyzed and the data will be reported within sixty days of receipt of the samples. Digestates will be disposed upon completion of data review and approval.

3. Approval must be granted by Chief, CLP lab before the required analyses may be considered to be complete for each sample. Such approval will be based upon the report of complete and appropriate data, as described in SOP 2130.8A.

VI. Analytical Methodology

A. Preparation and analyses of the samples collected in this Study will be performed according to SOPs 3110.1A, 3110.3A, 3121.6A, 3121.8A,3121.11A, 3121.13A, the SOPs relating to analysis of environmental samples for Pb and Cd by Graphite Furnace Atomic Absorption (GFAA) Spectrometry. Use of GFAA will be necessary to meet the required levels of accuracy, precision, and sensitivity (detection limits) noted above. Laboratory Quality Control shall be performed per SOP 1610.1B; data will be reviewed according to SOP 1330.2A.

VII. Data Reduction and Validation

A. The reporting units and data reduction procedures used will be those specified in the action level table in Section III.E above. The data will be reviewed per SOP 1610.1B and 1330.2A, with this document being the basic reference for data usability.

VIII. Data Reporting

After data review, reduction, and validation, as a primary deliverable, a disk or "tape" of the data shall be supplied to EPA within 120 days of the completion of the field sampling operations.

for transmittal to ATSDR. A draft report summarizing the environmental data collected and an evaluation of the quality of such data shall be supplied to EPA within 150 days of the completion field sampling operations, for transmittal to the individual(s) noted in Section II above. The report will include statements that samples do or do not meet applicable criteria as spelled out in this document and applicable SOPs. Following receipt of U.S. EPA and ATSDR comments on the draft report, a final report shall be submitted to Brad Bradley within 30 days.

IX. Quality Control (QC) Checks

A. The laboratory QC procedures which are incorporated into specific methodologies referenced in Section VI and in SOP 1610.1B will be followed, to include:

1. Method Blanks, at least once per sample preparation batch or one per day (which ever is more frequent), for each medium.

2. Laboratory Duplicates, on 5% of the field samples analyzed or one per sample batch (which ever is more frequent) for each medium.

3. Duplicate Matrix Spikes, on 5% of the field samples analyzed or one set per sample batch (which ever is more frequent). This data will be used to estimate both the precision and accuracy of the reported data.

B. Field QC will include 10% duplicates, field blanks (at least one per day) and Performance Evaluation samples or duplicate field spike soils samples, as discussed in SOP 2110.2A.

X. Performance and System Audits

Neither field audits nor laboratory audits beyond the routine QA/QC oversight of the appropriate supervisors is anticipated for this project, unless specifically determined to be necessary.

XI. Preventive Maintenance (PM)

Preventive maintenance will be performed in accordance with manufacturer's specifications and applicable regional policies and SOP's.

XII. Analysis of QC Data

All QC data will be reviewed by E&E personnel using the calculations and statistical methods specified in Region V protocols. This review will include an evaluation of accuracy, precision, completeness, sample representativeness, and comparability, using the methods discussed in Section IX., Internal Quality Control Checks, above.

XIII. Corrective Actions

All questionable data will be tracked by the analyst at the CLP lab to identify potential out-of-control situations. When an out-of-control situation is identified, it will be address per SOP 1610.1B.

Appendix I—Method 3050-Acid Digestion of Sediments, Sludges, and Soils

METHOD 3050

ACID DIGESTION OF SEDIMENTS, SLUDGES, AND SOILS

1.0 SCOPE AND APPLICATION

1.1 This method is an acid digestion procedure used to prepare sediments, sludges, and soil samples for analysis by flame or furnace atomic absorption spectroscopy (FLAA and GFAA, respectively) or by inductively coupled argon plasma spectroscopy (ICP). Samples prepared by this method may be analyzed by ICP for all the listed metals, or by FLAA or GFAA as indicated below (see also Paragraph 2.1):

FLAA		GFAA
Aluminum	Magnesium	Arsenic
Barium	Manganese	Beryllium
Beryllium	Molybdenum	Cadmium
Cadmium	Nickel	Chromium
Calcium	Potassium	Cobalt
Chromium	Sodium	Iron
Cobalt	Thallium	Molybdenum
Copper	Vanadium	Selenium
Iron	Zinc	Thallium
Lead		Vanadium

2.0 SUMMARY OF METHOD

2.1 A representative ¼ to ½ g (wet weight) sample is digested in nitric acid and hydrogen peroxide. The digestate is then refluxed with either nitric acid or hydrochloric acid. Dilute hydrochloric acid is used as the final reflux acid for (1) the ICP analysis of As and Se, and (2) the flame AA or ICP analysis of Al, Ba, Be, Ca, Cd, Cr, Co, Cu, Fe, Mo, Pb, Ni, K, Na, Tl, V, and Zn. Dilute nitric acid is employed as the final dilution acid for the furnace AA analysis of As, Be, Cd, Cr, Co, Pb, Mo, Se, Tl, and V. A separate sample shall be dried for a total solids determination.

3.0 INTERFERENCES

3.1 Sludge samples can contain diverse matrix types, each of which may present its own analytical challenge. Spiked samples and any relevant standard reference material should be processed to aid in determining whether Method 3050 is applicable to a given waste.

4.0 APPARATUS AND MATERIALS

4.1 Conical Phillips beakers: 250-mL.
4.2 Watch glasses.
4.3 Drying ovens: That can be maintained at 30°C.
4.4 Thermometer: That covers range of 0 to 200°C.
4.5 Whatman No. 41 filter paper (or equivalent).
4.6 Centrifuge and centrifuge tubes.

5.0 REAGENTS

5.1 ASTM Type II water (ASTM D1193): Water should be monitored for impurities.

5.2 Concentrated nitric acid, reagent grade (HNO_3): Acid should be analyzed to determine level of impurities. If method blank is <MDL, the acid can be used.

5.3 Concentrated hydrochloric acid, reagent grade (HCl): Acid should be analyzed to determine level of impurities. If method blank is <MDL, the acid can be used.

5.4 Hydrogen peroxide (30%) (H_2O_2): Oxidant should be analyzed to determine level of impurities.

6.0 SAMPLE COLLECTION, PRESERVATION, AND HANDLING

6.1 All samples must have been collected using a sampling plan that addresses the considerations discussed in Chapter Nine of this manual.

6.2 All sample containers must be prewashed with detergents, acids, and Type II water. Plastic and glass containers are both suitable. See Chapter Three, Section 3.1.3, for further information.

6.3 Nonaqeuous samples shall be refrigerated upon receipt and analyzed as soon as possible.

7.0 PROCEDURE

7.1 Mix the sample thoroughly to achieve homogeneity. For each digestion procedure, weigh to the nearest 0.01 g and transfer to a conical beaker a 0.25- 0.50 g portion of sample.

7.2 Add 2 mL of 1:1 HNO_3, mix the slurry, and cover with a watch glass. Heat the sample to 95°C and reflux for 10 to 15 min without boiling. Allow the sample to cool, add 1 mL of concentrated HNO_3, replace the watch glass, and reflux for 30 min. Repeat this last step to ensure complete oxidation.

NIST SRM #	METHOD	206Pb/204Pb	207Pb/204Pb	208Pb/204Pb	Pb(ppm)
277	HF/HNO3	18.992	15.596	38.590	607.8
	EPA3050	18.876	15.670	38.637	557.7/9188
1633A	HF/HNO3	18.881	15.634	38.675	72.59
	EPA3050	18.638	15.445	38.413	19.20/274.9
1646	HF/HNO3	18.767	15.551	38.350	27.76
	EPA3050	18.363	15.588	38.043	32.33/162.4
2704	HF/HNO3	18.681	15.558	38.215	159.2
	EPA3050	18.811	15.641	38.276	138.0/712.7

EXPLANATION

METHOD: HF/HNO3 Sample attacked by a 4:1 48% HF-8N HNO3 mixture; all samples were entirely digested with the exception of NIST SRM # 277.

EPA3050 Sample attacked by EPA Method 3050 which is basically an acid (HNO3/HCl) + H2O2 procedure; the specific method is attached.

Sample weights ranged from 240 to 260 mg with the exception of NIST SRM 1646 where 120 to 130 mg were used (circa 50% of the certification weight).

Pb ISOTOPIC RATICS: Ratios are precise to ± 0.10% at the 95% confidence level (2 sigma standard error of the mean) and are accurate to better than 0.10% based upon their normalization to NBS SRM 981.

Pb CONCENTRATIONS: Concentration errors are better than 2%. The two values reported for the EPA 3050 method are calculated from (1) the total weight of sample subjected to attack (i.e. 120 - 260 mg; first value) and (2) the total weight of sample actually digested by the EPA 3050 method of extraction (typically 5 - 20%). Note that the EPA 3050 method utilizes the total weight of sample subjected to attack.

MAJOR CONCLUSION: The HF/HNO3 method yields results within the certified Pb concentration error limits while EPA 3050 does not. In one instance (NIST SRM 1646), EPA 3050 yields approximately 20% more Pb than the certified value. The distinct differences between the Pb isotopic ratios obtained from th same sample using the two methods indicates that very different Pb reservoirs are being extracted by the two methods.

7.7 Calculations:

7.7.1 The concentrations determined are to be reported on the basi of the actual weight of the sample. If a dry weight analysis is desired then the percent solids of the sample must also be provided.

7.7.2 If percent solids is desired, a separate determination o percent solids must be performed on a homogeneous aliquot of the sample.

8.0 QUALITY CONTROL

8.1 For each group of samples processed, preparation blanks (Type I water and reagents) should be carried throughout the entire sample preparatio and analytical process. These blanks will be useful in determining if sample are being contaminated.

8.2 Duplicate samples should be processed on a routine basis. Duplicat samples will be used to determine precision. The sample load will dictate th frequency, but 20% is recommended.

8.3 Spiked samples or standard reference materials must be employed t determine accuracy. A spiked sample should be included with each group o samples processed and whenever a new sample matrix is being analyzed.

8.4 The concentration of all calibration standards should be verifie against a quality control check sample obtained from an outside source.

9.0 METHOD PERFORMANCE

9.1 No data provided.

10.0 REFERENCES

10.1 None required.

Using a ribbed watch glass, allow the solution to evaporate to / mL without boiling, while maintaining a covering of solution over the bottom of the beaker.

7.3 After Step 7.2 has been completed and the sample has cooled, add / mL of Type II water and / mL of 30% H_2O_2. Cover the beaker with a watch glass and return the covered beaker to the hot plate for warming and to start the peroxide reaction. Care must be taken to ensure that losses do not occur due to excessively vigorous effervescence. Heat until effervescence subsides and cool the beaker.

7.4 Continue to add 30% H_2O_2 in 1-mL aliquots with warming until the effervescence is minimal or until the general sample appearance is unchanged.
NOTE: Do not add more than a total of 3 mL 30% H_2O_2.

7.5 If the sample is being prepared for (a) the ICP analysis of As and Se, or (b) the flame AA or ICP analysis of Al, Ba, Be, Ca, Cd, Cr, Co, Cu, Fe, Pb, Mg, Mn, Mo, Ni, K, Na, Tl, V, and Zn, then add / mL of concentrated HCl and 3 mL of Type II water, return the covered beaker to the hot plate, and reflux for an additional 15 min without boiling.
Particulates in the digestate that may clog the nebulizer should be removed by filtration, by centrifugation, or by allowing the sample to settle. Evaporate to dryness, cover, store.

Appendix J—Comments On Madison County Lead Exposure Study, Granite City, Illinois

May 23, 1994

COMMENTS ON
MADISON COUNTY LEAD EXPOSURE STUDY, GRANITE CITY, ILLINOIS

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INTRODUCTION: ORGANIZATION OF THE REPORT

These comments are divided into two main parts, Part 1: General Issues, and Part 2: Detailed Comments. Our comments address many substantial areas of inadequacy in the Madison County Lead Exposure Study report. At the very least, the report needs much more extensive discussion of the differences between study design and actual implementation, better presentation of results, more appropriate statistical analyses of data, and major revisions of the interpretation of the results. Part 1 provides an overview of our concerns. The most important sections are:

1. Implementation of Study Design
2. Field Sampling and Analysis of Samples
3. Statistical Analyses of Data
4. Presentation of Results
5. Interpretation and Conclusions
6. External Review Process

Subsections of each Section are numbered for easier reference. Part 2 of these comments consists of specific comments on certain comments in the text or supporting material, numbered sequentially for easier reference.

PART 1: GENERAL ISSUES

1. IMPLEMENTATION OF STUDY DESIGN

1.1. Recruitment of Subjects

We believe that the report should discuss the possible biases due to recruitment which are inherent in this type of study. While several goals may be defined for the recruitment process, we would expect the process to provide a valid representative sample of children who live in the area of Madison County that is expected to be most heavily impacted by environmental lead exposure. There were a substantial number of households not contacted or no-shows. The report notes that many of these had no telephone. It is likely that many of these households consisted of families with lower socio-economic status (denoted SES in our comments). In other studies, children in families with lower socioeconomic status are known to have a higher risk of elevated blood lead. It is likely that many of these no-contact households were located in older parts of the community and may have had higher soil lead or lead paint exposure. There was also a very high rate of refusals, 266 out of 790 households. Some information on the location of these households would be very useful in determining whether there is a differential rate of refusals or non-contact households that may be confounded with lead exposure.

1.2. Omission of Pontoon Beach Subjects

The study design clearly identifies the importance of a control group. We were disappointed to see that the Pontoon Beach residents were not evaluated. In spite of the fact that these residents lived in newer houses or in a trailer park and were more distant from Granite City, they would still have provided a useful control group with only a modest additional effort.

1.3. Resampling of Children with Elevated Blood Lead

While we are sympathetic to the investigators' concerns about children with elevated blood lead (hereafter defined as blood lead concentration of 10 ug/dl or higher) and are supportive of resampling, this sample is almost useless for inferential purposes. The first difficulty is the well-known problem of "regression to the mean" in follow-up studies. What this means is that if there are repeated measurements on the same child, then even if the mean value for the population remains unchanged between the first and second samples, those children who tested above average on the first test will score closer to the average on the second test, and those children who scored below the average on the first test will tend to score closer to the average on the second test. Thus, the second sample is highly biased for inferential purposes because it includes a few of the siblings of those children with elevated blood lead. Even the siblings with blood lead less than 10 ug/dl at the first test are likely to have blood lead concentrations that are higher than average since they are exposed to the same environment as the siblings with elevated blood lead. The report does not provide any information about this group.

A second difficulty is that in many other studies, children who were tested in winter had lower blood lead concentrations than children who were tested at the summertime peak, typically

by about 30 percent. Even allowing for the hypothetical possibility that there may be a late-winter peak (this hypothesis has not been tested generally), that winter peak must be substantially lower than the summer peak.

Therefore, an observed decrease in blood lead concentrations following intensive education and counselling with the parents or caretakers of the children cannot be demonstrated by this resampling scheme. We do not disagree with the report's hypothesis that parental counselling and education may be effective in reducing blood lead in children exposed to environmental sources of lead. However, this study was not designed to test that hypothesis and cannot be used to do so, nor to estimate the effects of such intervention. A study designed for that purpose would include another group of children with low blood lead concentrations. The study would then randomly assign families to the 'treatment group' (parental education and counselling about environmental lead hazard reduction), a 'positive control group' (parental education and counselling about other child care issues, not emphasizing lead exposure), and a 'negative control group' (no parental education or counselling). A design of this type would control for seasonal changes and age-related changes in blood lead. It should also be noted that intervention has been going on in the area for some time, and the children who took part in this study may have been subject to extensive education prior to the first sampling of blood lead as well.

Since the resampled children in the Madison County study are used to reach some very broad and general conclusions, a much more complete description of the data should have been provided, such as bivariate graphs plotting the blood lead concentrations in September and December. Better yet, with only 61 such children, a table of data values could have been provided.

2. FIELD SAMPLING AND ANALYSIS OF SAMPLES

2.1. Household Dust Samples

The study protocol required collection of 3 to 5 grams of dust using what appears to be an ordinary "dust-buster" type of vacuum cleaner. The priority sequence of collection is well defined (main entrances, two child play areas, and then additional samples from secondary entrances, window sills, furniture, and carpets). However, this differs in many ways from the household dust collection protocols used in other studies. The total dust requirement is much larger than in many studies such as the Urban Soil Lead Abatement Demonstration Project (denoted USLADP) studies in Baltimore, Boston, and Cincinnati. The collection of such a large quantity of dust using a vacuum cleaner of unknown (but presumably low) efficiency will almost certainly require collection of dust samples from the lower-priority areas. We have questions as to how to relate these samples to the child's exposure, which is most likely to occur in the primary play areas (typically, the child's bedroom, the living room or other area used for watching television, and the kitchen). We would have preferred to see the collection of individual samples rather than composite samples of floor dust and window sill dust, since window sill dust often has a much higher concentration and lead loading than floor dust. Our concerns are that this procedure may systematically bias the dust lead measurements, or at worst will greatly increase the variability of such measurements. The report points out this concern as well. Our preference would be to collect separate dust samples from entrances, window sills, window wells, and floors (these may be composited within each type of surface).

2.2. Quality Control for Dust Lead and Soil Lead Analyses

While adequate internal QA/QC procedures for dust lead and soil lead have been defined, it would be useful to have independent external analyses for some of the archived samples. Our experiences in the USLADP studies is that even very good laboratories may not be able to exactly reproduce the concentrations measured at other labs, and that some kind of calibration with respect to consensus values may be needed. It would have been desirable to have done this during the course of the analyses for the Madison County study so as to facilitate comparison with other studies. A reanalysis of a portion of the samples may produce useful information.

2.3. Soil Sample Preparation

The soil samples were apparently not sieved. This makes it more difficult to interpret the results, since small soil particles that can adhere to the child's hands often have higher lead concentrations than larger particles. The removal of paint chips from the soil samples may also have removed a substantial amount of information about sources of lead in surface soil, especially if all samples were not treated equally.

2.4. House Condition and Paint Condition

No examples are presented of what "good" or "poor" condition means. Reproducing this subjective assessment might be impossible. Was yard condition also evaluated? These questions warrant some discussion in the report.

3. STATISTICAL ANALYSIS OF DATA

3.1. There is a Lack of Information about Dependence on Age

The authors note that the incidence of elevated blood lead concentration is at a maximum between ages 1.5 and 2.5 years. However, it appears that when blood lead models are adjusted for age as shown in their Table 10, the adjustment is linear (monotone) and therefore cannot reproduce a peak age. Most studies find large differences at different ages. At least some of the analyses should look at age effects that may be non-linear, either as continuous covariates or in categories (for example, by year or by intervals such as age < 12 months, 12 to 35 months, > 36 months etc.).

3.2. There is Inadequate Spatial Resolution of Demographics and Lead Exposure

The report is almost completely lacking any information about spatial relationships, apart from distance from the smelter. The division of the study area into concentric rings is not defensible. Even assuming that the smelter is a significant point source of environmental lead, it is almost certain that the lead from the smelter was not deposited in a circular pattern around the smelter. Lead particles from the smelter may be transported to a child's residence in many ways: from airborne transport; from rain water runoff; on cars or trains that collected lead dust while near the smelter; in bulk soil transported for use as fill material near the residence; on clothing, shoes, hair, skin, and nails of lead workers or other adults; on outdoor pets. The wind does not blow equally often from all directions; water does not flow uphill; railroad tracks and major highways are not distributed uniformly in the community. There is thus no reason to believe that soil and dust lead will occur in concentric concentration isopleths around the smelter. It is also known that battery casings were used as fill material in various parts of the community, especially the Venice area. This is expected to produce a dispersed random (but non-uniform) additional component of soil lead in Madison County.

An even more important reason for considering other spatial groupings is that the population of potentially exposed children is probably not uniformly distributed around the smelter. The older parts of Granite City are probably closest to the smelter. Thus, housing age, housing condition, and environmental lead from smelter emissions are confounded. Older housing may contain a higher proportion of low-income families and a higher proportion of families with multiple children less than 7 years of age, thus exposing more children to lead than housing units farther from the smelter.

Another factor that may be associated with location is ethnicity, which some studies have found to be associated with elevated blood lead concentration. The clusters of housing where children with blood lead above 10 ug/dl live is clear in the map in Figure 1 of the report, but the reader can only speculate on what these clusters signify. The information was not used in the statistical analyses, apart from distance to the Taracorp facility.

It would be far more helpful to have geographic information about soil and dust lead levels on a smaller scale, say in about 10 contiguous neighborhoods with about 50 children each, including a clear identification of outlying communities such as Madison, Venice, and including Pontoon Beach. One clustering method that would be useful is to identify neighborhoods by contours or concentration isopleths for soil lead. While the authors expressed some hope that the concentric rings of about 1 km radius would do this, we are not convinced that this approach

succeeded. The irregularity in the distances for rings 1 to 3 (0.8 to 1 km) suggest that some neighborhood grouping may have been done, but this is not shown on the map in Figure 1 of the report.

It is well known that important exposure and uptake characteristics of soil lead particles, such as the relative contribution of soil lead to household dust lead and the bioavailability of the soil particles, may depend on properties such as particle size, chemical speciation, and mineral matrix. If there is any possibility that these properties, which affect the relationship between blood lead and soil lead, differ from place to place within the study area due to differences in the primary source of soil lead, then some appropriate basis separating the study area into sub-areas with similar characteristics of exposure and uptake must be found. USEPA uses as a consistent community criterion that less than 5% of the children under the age of six may have blood lead levels equal or greater than 10 ug/dl. In this study community, the entire community blood lead level is high (the percentage of children with a blood lead level of 10 ug/dl or above is 16 percent, or 78/490), and in some areas near and downwind of the smelter it may be even higher, as shown by the map (Figure 1) on the page marked '80' which is actually page 74 of the report. In order to test the feasibility of our recommendation, we did the following simple exercise. We divided the area shown in Figure 1 into 5 spatially contiguous "neighborhoods", as shown on Comments Figure 1, attached. Area 1 extends northeast from the NL Industries/Taracorp facility (NL site) 7 blocks; prevailing winds and proximity to the site make this area a plausible location for deposition of particles. Area 1 is shown by diagonal lines from upper left to lower right in Comments Figure 2. Area 2 is further north and east than Area 1, and is shown by diagonal lines from lower left to upper right in Comments Figure 1. Area 3 is northeast of Area 1 and is at least 3 blocks northeast of the NL site. Area 4 extends south of the site up to about 12 blocks or 1 mile and includes mostly the Madison community. Area 5 is further south and includes mostly the Venice Community. Area 3 is shown by vertical lines on Comments Figure 1, and Area 4 by horizontal lines.

We then expanded the map 200% using a photocopier, as shown in Comments Figures 2, 3, and 4. Even so, it was almost impossible to accurately determine all of the housing units where pre-school children with elevated blood lead resided, shown as open square symbols, and the housing units with no such children shown by solid circle symbols. We counted the number of housing units in each area, as shown in Comments Table 1. The results are that 26 percent of the units in Area 1 have children with elevated blood lead (10/39 units). Only 7 perecent of the children in Area 2, in the same direction but more distant from the NL Industries site than Area 1, have elevated blood lead (9/127 units). Area 3, which is about as close to the site as Area 1 but in a direction which is predominantly upwind, has 12 percent of the units with children who have elevated blood lead. Areas 4 and 5 have comparable incidences, 13 percent of the units in Area 4 (8/60 units) and 14 percent of the units in Area 5 (3/21 units), even though Area 4 housing is about as close as Area 1 housing. The percentage of housing units in Area 1 downwind of the site with lead-burdened children, 26 percent, is significantly higher than the percentage of units about the same distance south of the site in Area 3, 12 percent. This demonstrates that distance alone does not describe the distribution of elevated blood lead in the study area.

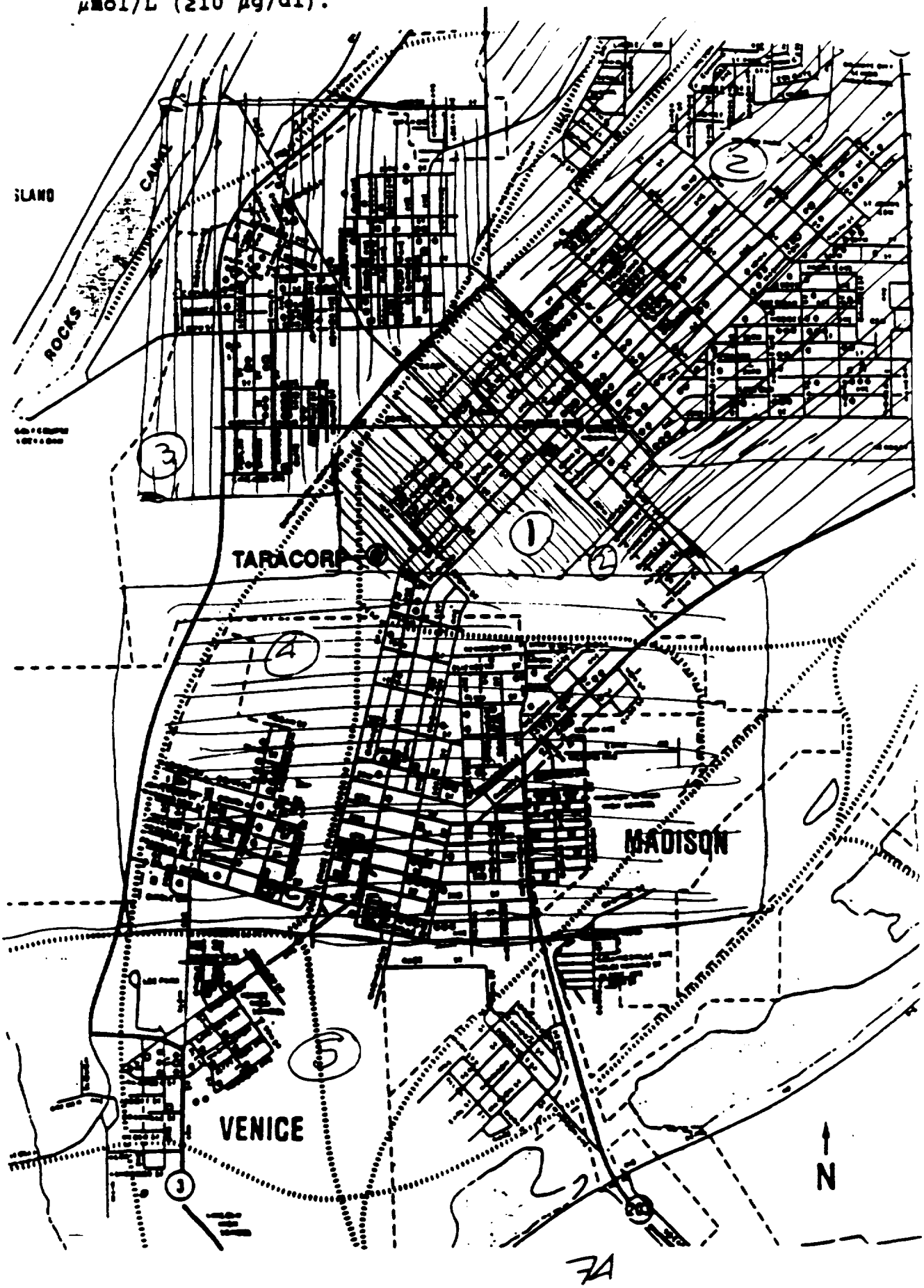
There is no reason why the reader of this report should have to work so hard to extract this absolutely vital information.

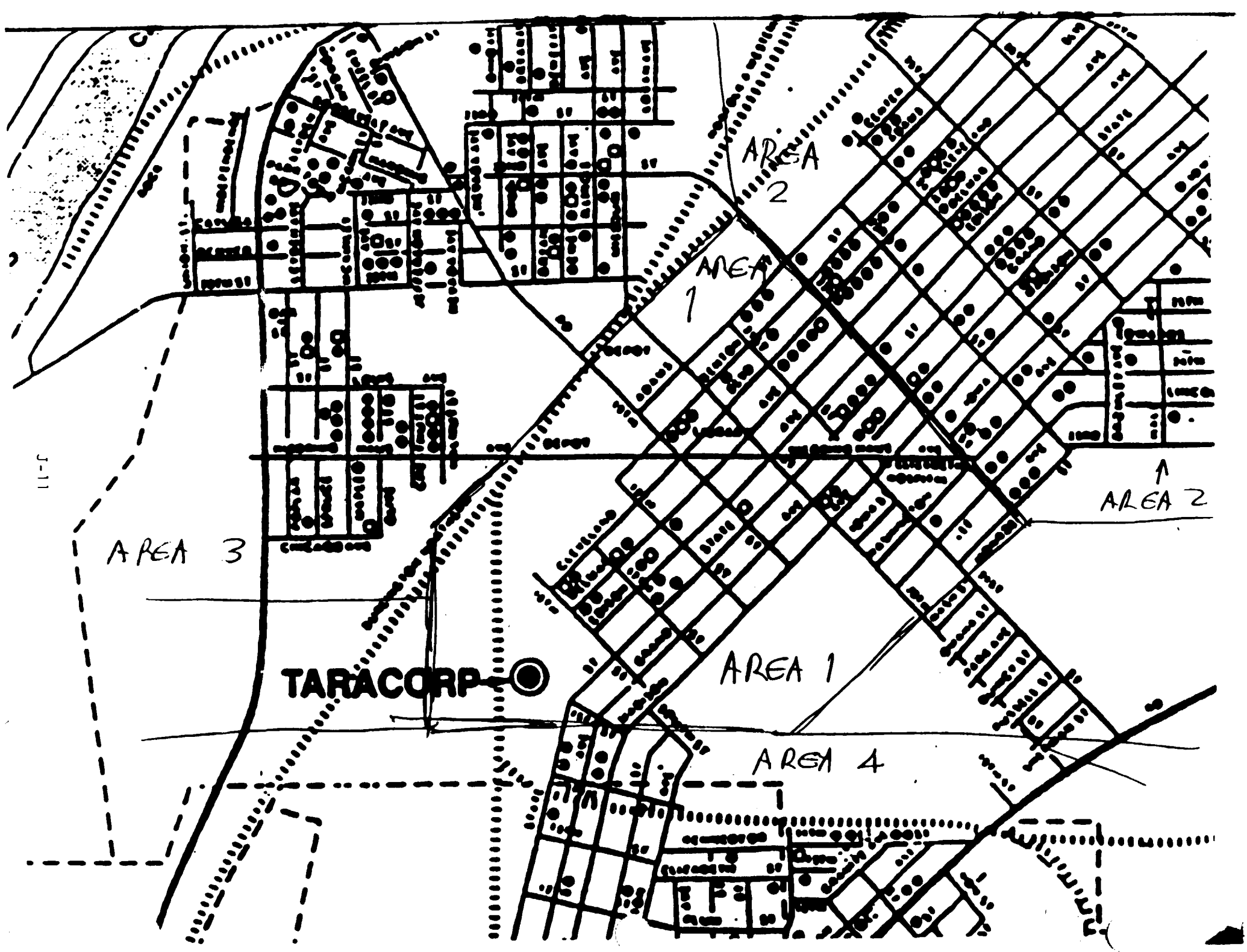
COMMENTS TABLE 1

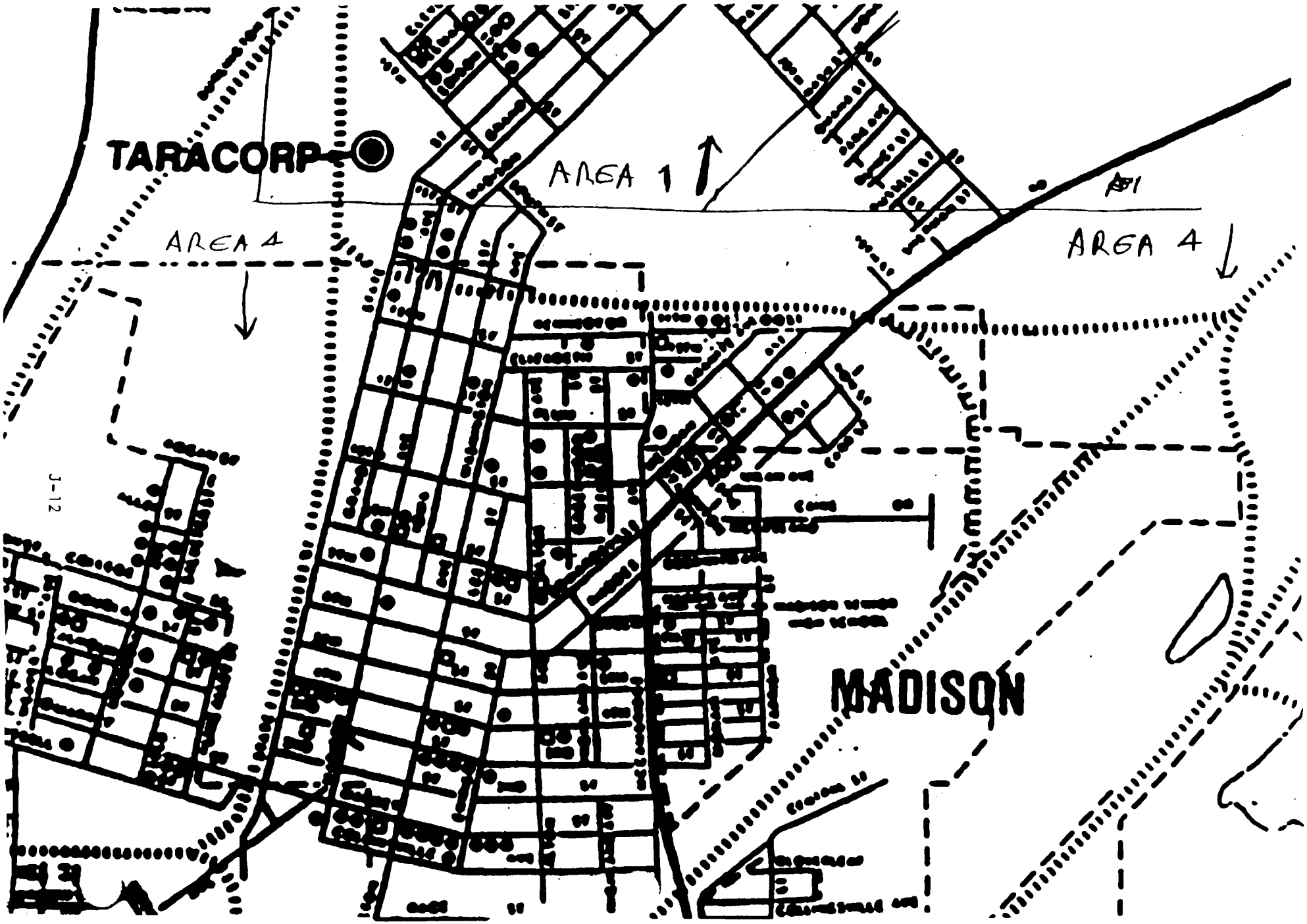
Percent of participating housing units that have at least one pre-school child whose blood lead concentration is greater than or equal to 10 ug/dl. Based on visual counting from map in the Madison County Lead Exposure Study.

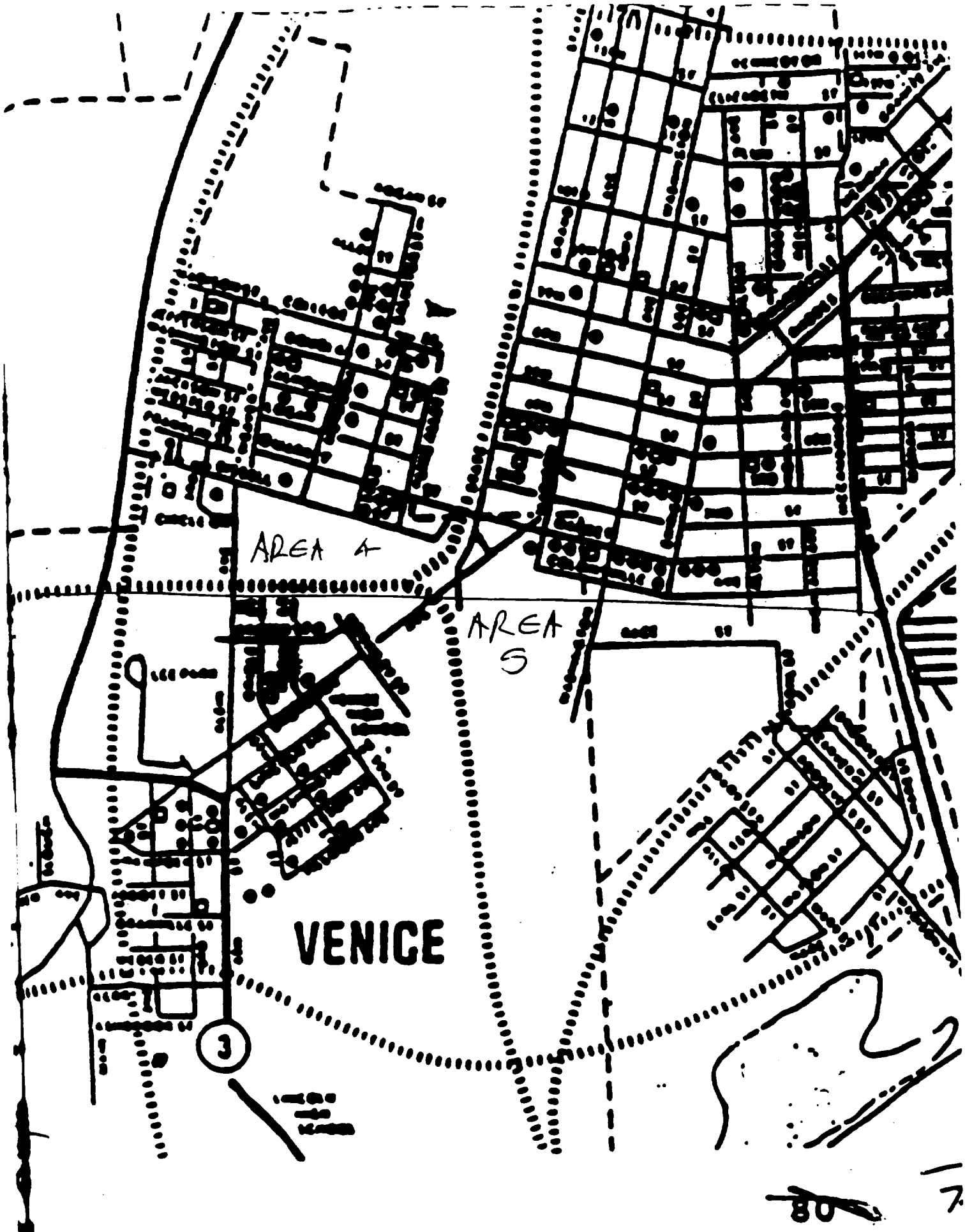
AREA	UNITS WITH CHILD BLOOD LEAD ≥ 10 ug/dL	UNITS WITH NO CHILD BLOOD LEAD ≥ 10 ug/dL	TOTAL UNITS	PERCENT OF UNITS WITH CHILD BLOOD LEAD ≥ 10
1	10	29	39	26 %
2	9	118	127	7 %
3	9	64	73	12 %
4	8	52	60	13 %
5	3	18	21	14 %
ALL MAP	39	281	320	12 %

residents. The closed circles represent residents with children with blood lead levels <0.48 µmol/L (<10 µg/dl). The open squares represent houses with children with blood lead levels of ≥0.48 µmol/L (≥10 µg/dl).




AREA 2
AREA 1
AREA 2
AREA 3
TARACORP
AREA 1
AREA 4


TARACORP
AREA 1
AREA 4
AREA 4
MADISON
J-12


AREA A
AREA S
VENICE
3
80

3.3. The Regression Model in the Report Implies Unrealistic Relationships between Blood Lead and Environmental Lead

Lead exposure from multiple media is essentially additive. Therefore, the relationship between blood lead and environmental lead can be well approximated by a linear relationship over a wide range of concentrations, as shown on p. VI-31 in (ATSDR 1988). The statistical reasons for a logarithmic transformation of this relationship are discussed in detail in (Angle et al. 1984) and in (USEPA 1986a) as cited in (ATSDR 1988); the Angle et al. study is also cited in the paper (Weitzman et al. 1993) referenced by the authors. The correct method of fitting the relationship is shown in detail.

The statistical model used by these authors is a serious mis-specification of the correct relationship and may be largely responsible for some of the estimation and hypothesis testing problems that they encountered. Their model may also generate extremely misleading predictions or projections. To illustrate this point, let us use their hierarchical regression model whose coefficients are given by Model 2 on page 70, Table 10, of the Granite City Lead Exposure Study. We may express the model by the equation:

$$\log(\text{blood lead}) = 0.58 + 0.03 \log(\text{water lead}) + 0.03 \log(\text{CXI}) - 0.01 \log(\text{CXO}) +$$

$$0.3\ (\text{Condition code}) - 0.16\ (\text{Refinish Code}) + 0.17 \log(\text{soil lead}).$$

When this model is converted back to the blood lead scale by calculating the exponential function of both the right-hand and left-hand sides of this equation, we have a multiplicative equation, using * to denote multiplication:

$$\text{blood lead} = 1.786 * (\text{water lead})^{0.03} * (\text{CXI})^{0.03} * (\text{CXO})^{-0.01} * (\text{Condition code})^{0.3} *$$

$$(\text{Refinish code})^{-0.16} * (\text{soil lead})^{0.17}.$$

We see that if water lead concentration could be reduced as low as one wanted, nearly down to 0 ppb, then the blood lead predicted by the authors' equation would go down to 0 without controlling the lead in interior lead-based paint (CXI), in exterior lead-based paint (CXO), or lead in soil. This is, of course, absurd. A similar reductio ad absurdem would apply to the other models for log(blood lead) developed by the authors. A model should have been developed so as to avoid these paradoxes.

3.4. The Contribution of Soil Lead to Blood Lead and to Dust Lead is not Correctly Calculated

The hierarchical regression model proposed in the report and described in Table 11 provides an extremely misleading representation of the relationship of soil lead to blood lead. Combination of the models in Tables 10 and 12 of the report provides a much more accurate description of the inter-relationships between blood lead and environmental lead. These analyses show that the indirect relationship between soil lead and blood lead, primarily through dust lead but confounded with other variables in the analyses, may be the most important component of

the blood lead model.

Even if the regression model used in the report were correct (which we have shown to be false), the method used to attribute blood lead to various source terms is not correct. In the first place, the real-world significance of a regression term depends both on its magnitude or effect size, and on its statistical significance. The use of R^2, or the percentage of variance explained by a regression model, describes neither of these. No environmental lead model can be expected to explain an extremely high percentage of the variation in blood lead because this variation is caused by inter-individual differences in lead ingestion, lead absorption, and lead distribution or biokinetics. For a given set of exposure conditions such as environmental lead concentrations in various media, some children who ingest a large amount of lead will have high blood concentrations, and children who ingest a small amount of lead in the same environment will have much smaller blood lead concentrations. As discussed below in Section 3.6, these inter-individual differences are multipliers of environmental lead concentration, and so will contribute about the same of variance to the logarithm of blood lead, whatever the environmental lead concentration. In fact, the 37 percent of variance in the logarithm of blood lead that is accounted for by the regression model in Table 10 of the report (p. 70) is quite comparable to that found in most other studies of the logarithm of blood lead vs. environmental lead.

The single most important predictor of log(blood lead) in Table 10 is the logarithm of the dust lead loading, accounting for 17 percent of the variance by itself. However, the attribution of blood lead increments to other factors are also partial indicators of soil lead or dust lead exposure, such as the variables 'Recent Remodeling' (which suggests recent historical exposure to fine dust particles or possibly surface soil debris), 'Distance' (which shows decreasing blood lead with increasing distance from the smelter and may be a surrogate for smelter-derived airborne deposits of lead on soil and in house dust). To some extent, SES-related variables such as 'Years of Education' and 'Rent or own home', and other socio-demographic variables such as 'Ethnicity' are confounded with soil lead and dust lead. Thus, 17 percent is the minimum contribution of dust lead and soil lead to log(blood lead).

Likewise, soil lead concentration is the most important predictor of dust lead loading, based on Model 2 in Table 12 on page 72 of the report (presumably the logarithm of the composited soil lead concentration, misspelled as 'Soil composition' in Table 12). In fact, soil lead is such a good predictor of dust lead that including soil lead in the dust lead loading equation reduces the contribution of exterior lead-based paint (denoted CXO in Table 12) from statistically significant ($P = 0.02$ in Model 1) to statistical non-significance ($P = 0.2$ in Model 2). It is clear that CXO is thus a partial surrogate for soil lead, probably because lead from deteriorating exterior lead-based paint has been identified as one of the sources of residential soil lead in almost all studies. Soil lead and CXO are correlated, but exterior lead-based paint is probably only a partial contributor to soil lead; the report did not investigate this important question. Other variables used in Table 12 are probably confounded with location and house age, such as the variables 'Condition of residence' and interior lead paint 'Log of CXI'. It is clear that the actual contribution of soil lead to dust lead is much larger than 6 percent of the variance, but the information presented in the report does not allow an estimate of the contribution. The large amount of residual variation in dust lead loading may be attributable to variability in total dust loading which depends on inter-unit differences in the effectiveness and frequency of house cleaning. Dust lead concentrations often show a higher correlation with soil lead concentration than does dust lead loading.

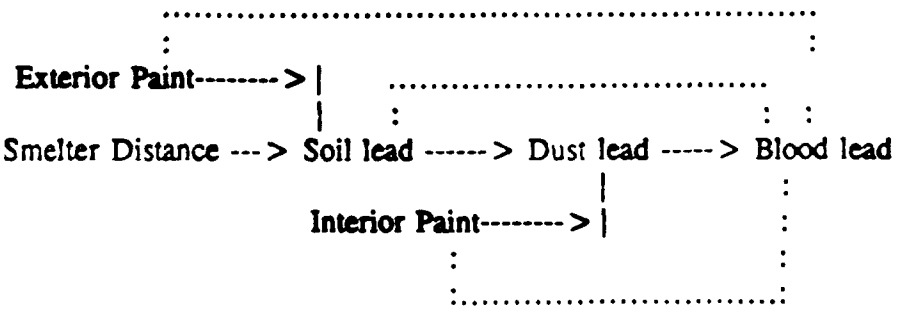
Even if these analyses were correct (see Section 3.3 above), the report has greatly

underestimated the real contribution of soil lead to dust lead, and greatly underestimated the contribution of dust lead to blood lead. Thus, the report has incorrectly used its own analyses. A more complete use of these analyses would demonstrate a very different interpretation - that soil lead is at least a highly significant indirect contributor to blood lead through the dust lead pathway. While the report asserts the importance of this causal pathway in several places, the quantitative significance and magnitude of the indirect pathway from soil to dust to blood is not correctly calculated.

3.5. The Report Does Not Correctly Model Multi-Media and Multi-Pathway Lead Exposure

Lead exposure from soil and paint is a multi-media and multi-pathway process, with household dust as the primary exposure vector for young children. Therefore, any of these sources has both direct pathways and indirect pathways contributing to childhood lead exposure. Data analyses that fail to recognize that both direct exposure and indirect pathways through dust or soil may both contribute cannot adequately characterize the child's total exposure. This is shown in the ATSDR Report on page II-2 and discussed on pages VI-29 through VI-32 therein. Much more extensive discussion is given in the references cited therein, particularly (Angle et al. 1984) (Bornschein et al. 1985, 1987ab) (Clark et al. 1985, 1987) (USEPA 1986a) (Walter et al. 1980). The Bornschein and Clark papers discuss environmental pathway models, albeit with an incorrect model specification.

The most plausible explanation of the blood lead vs. dust lead and soil lead relationships is that lead in soil is probably a major reservoir for lead in household dust and so the indirect exposure pathway soil -> dust -> blood should have been used as the basis for blood lead models. The report notes in several places that "confounding" between household dust lead and lead in soil complicate estimates of the soil effect on blood lead. To a large extent, household dust lead is the most proximate (i.e, the most highly correlated) of the environmental lead concentration or loading variables, based on Table 10 and on the correlations reported in the text on pp. 38-39. Dust is the primary exposure vector. However, dust lead loading is fairly highly correlated with soil lead. Dust lead loading is better correlated with soil lead than with interior lead paint loading in Table 12 on p. 72, but these two variables along with condition of the house allow a fairly good estimate of dust lead loading. It appears then that a pathway model of the following type may be adequate:



The direct pathway from soil lead to blood lead may be less significant in this Granite City study

than the indirect pathway. The strength of the pathways can be estimated and tested for statistical significance using structural equations models or similar techniques. This approach would be far more useful in identifying appropriate goals for environmental intervention.

3.6. The Report Does Not Use Individual Behavioral Variables to Reduce Variance in Blood Lead

While frequently noting the relatively low R^2 values achieved by the statistical models for blood lead, the report overlooked the basis for this fact and its implications for statistical data analysis. The basic problem is that blood lead levels are determined by other factors as well as by environmental lead, such as the child's behavior and biology. This can be stated very clearly and explicitly, from fundamental biological principles as described in the EPA Air Quality Criteria for Lead (1986) and elsewhere:

(blood lead increment, ug/dL) = (lead uptake, ug/day) / (blood lead clearance, dL/day)

= (lead intake, ug/d) * (lead absorption fraction) / (blood lead clearance, dL/d)

= (lead concentration, ug/g) * (intake, g/d) * (absorption) / (blood lead clearance, dL/d).

Thus, blood lead increments at any lead concentration in the medium are always proportional to three individually different parameters: the child's media intake or ingestion rate, the child's lead absorption fraction from that medium, and the child's blood lead clearance rate. The fact that lead concentration and other factors account for only a fraction of the variance in blood lead concentration is to be expected. This is irrelevant for risk assessment, however, since the mean blood lead concentration and the number of children with elevated blood lead concentration among a group of children with similar lead exposures can be many-fold different over a range of environmental lead exposures. Lead abatement actions such as the leaded gasoline phasedown of the 1980's and the soil and dust lead abatement in progress in the community of Kellogg, Idaho (which also has an inactive lead smelter) have been very effective in reducing child blood lead concentrations because they reduce the opportunity for exposure among those children who ingest and absorb the largest amount of lead.

This also implies that the regression model could have been improved by including cross-product or interaction terms. Some recent studies (Marcus 1992) suggest that the product of dust lead or soil lead and the relative frequency of mouthing non-food objects may be a better predictor of blood lead than dust lead concentration alone. This information exists in the individual child questionnaire, items 221-230 (pages C-18 and C-19 of the report). This kind of information has been found useful in many other studies, and should have been used in this study to reduce the inter-individual variability and thus better detect the most significant environmental contributions to child lead exposure.

This report needs a much more structured approach to the use of biological and behavioral information. The report notes that older housing, lower income, lower education, greater cigarette smoking, and other behavioral factors are associated with proximity to the smelter site. These factors may also be associated with greater ingestion of soil and dust, and greater oral contact with non-food objects. These socio-demographic factors may also be related

to poor nutrition, thus with increased ingestion (pica for calcium substitutes) and increased absorption of lead. The authors should consider the construction of composite variables such as principal components or factors that can be used to summarize these multi-collinear variables.

Ethnicity is often found to be a significant covariate. This is one of the most significant predictors of blood lead in the Madison County study, as shown in Table 10 of the report. Some effort should be made to identify important confounding variables in this relationship.

3.7. Multi-Collinearity Among Regression Predictor Variables

Many of the predictor variables used in the regression models are highly correlated with each other. This may cause estimates of regression coefficients to be 'unstable', and inflates the estimated standard errors and so reduces the statistical significance of the coefficients. Variance inflation and multicollinearity are discussed in most textbooks on regression methods. The SAS program used for the report has a number of appropriate diagostic statistics for variance inflation and multicollinearity detection that are described in SAS documentation. Many statisticians have eloquently described the problems of model specification using observational data with many correlated predictor variables, particularly econometricians such as Ed Leamer. A paper on modelling strategy that is well known to statisticians who are analysing lead exposure and health effects data was written by Kim Dietrich (1986), "The neurobehavioral effects of prenatal and early postnatal lead exposure", in Steve Schroeder (ed.) Toxic Substances and Mental Retardation. This paper also demonstrates the conceptual advantages of pathway models in a somewhat different context. The authors of this report need to rethink their whole modelling approach.

3.8. The Report Ignores Biases Due to Predictor Measurement

A statististical problem known as "measurement error" or "errors in [predictor] variables" complicates the estimation of regression coefficents. The standard assumption in ordinary least-squares linear regression techniques that were used in this report is that the variables used to predict the response variable (here, log blood lead) are known without error. In fact, environmental lead concentrations generally have a quite substantial measurement error. Part of this is really variability in the chemical analysis, but a larger part of the statistical variability in predictors such as soil lead concentration arises from the difficulty of trying to repeatedly sample at the same place as the original sample, and partly because there are real variations in soil lead at a site at different times. Analytical error could have been studied using the 39 duplicate soil samples. Statistical theory and empirical data shows that the effect of predictor measurement errors on bivariate regression (say, log blood lead vs. log soil lead) is to substantially reduce or attenuate the coefficient from the true value to a smaller value. This is a systematic effect, and produces a biased estimate of the regression coefficient. In multiple linear regression models, when there are measurement errors in several highly correlated predictor variables such as soil lead, dust lead, and house age, then the systematic bias may be either to attenuate or to inflate the regression coefficient, depending on the nature of the inter-correlations among the predictors. Statistical approaches are available (e.g. structural equation modelling methods) that may allow more reliable and less biased estimates of the regression coefficients. Expert statistical

assistance needs to be sought in assessing the likely impacts of measurement error in this study.

4. PRESENTATION OF RESULTS

4.1. Statistical Tables

Many statistical results reported in the text require tabulation. This includes statistics by ring, community, or neighborhood, of all of the variables used in the statistical models. The bivariate correlations reported in the text should also be presented in tabular form, including the statistical significance.

Many comparisons in the text are presented in terms of binary splits such as soil lead above/below 500 ug/g, blood lead above/below 10 ug/dl, and so on. The 2-by-2 tables corresponding to these binary splits would be very helpful in documenting the conclusions in the report.

Regression models should be described more completely, including partial R^2 for each covariate. Serious confounding could be characterized by the largest correlation coefficents among the partial regression coefficients. When variance inflation factors are high, some other regression approaches (such as principal components or ridge regression, easily implemented using SAS procedures) should be used to present an alternative set of relatively different regression coefficients, preferably in an Appendix. This would add a great deal of information with relatively modest efforts. There is not enough detail to assess the validity of any of the regression models. Outlier tests and similar diagnostics should be reported for the benefit of the technical readers. These can be appended as footnotes to tables of regression coefficients.

4.2. Graphs

The graphs in Figures 2a-2b are uninformative and should be replaced. Histograms of blood lead in intervals of 2 or 2.5 ug/dl would be just as easy to interpret and much more informative. Technical readers would probably appreciate a figure with superimposed cumulative distribution functions. Additonal information would be provided by stratifying the sample by age, and by location (community or neighborhood area).

4.3. Maps

Figure 1 is appallingly unclear, considering how much important and useful information it contains. Surely some better-quality method for map production can be found. It would be helpful to present a series of larger-scale maps showing details within each area, such as the location of schools and playgrounds, soil lead isopleths, and so on. Showing the housing units of the participating households, according as they do or do not contain lead-burdened children, would be invaluable to us. Another map showing the locations of non-participating households would be helpful. A number of graphical techniques are available for displaying statistical information on maps, as discussed in Edward Tufte's books. Implementing some of the techniques in SAS/GRAPH or other computer programs is not difficult.

4.4. Confidence Intervals

This report is totally deficient in giving confidence intervals for important effect size estimates or regression coefficients. Significance levels may be useful for hypothesis testing purposes, but these can be indicated by usual conventions such as one-asterisk superscripts for

P-levels between 0.01 and 0.05, and so on. Only readers with some statistical training can readily convert P-levels to confidence intervals.

5. INTERPRETATION AND CONCLUSIONS

pages 53-54, Conclusions: The conclusions do not follow logically from the analyses and findings in the report.

1. We disagree with the conclusion that "Blood lead levels of children under 6 years of age ... were, for the most part, below [10 ug/dl]". With 16 percent of children in the whole study area at or above 10 ug/dl, and a much higher percentage nearer the NL site, some intervention is needed. (clearly needed?)

2. We agree that "the highest percentage of children with elevated blood lead levels were from 1.5 to 2.5 years of age suggesting that this could be an optimal age for screening". However, this was not used in the regression analyses, since child age was entered as a monotone (non-peaked) predictor of blood lead. It is not clear that the writer of the conclusions was familiar with the results or methods in the text.

3. We agree that "Children with higher blood lead levels lived in houses near the closed smelter ...", but there is not enough information given in the report to reach this conclusion. In fact, the locations in which clusters of cases of elevated blood lead occur are never mentioned in the text. These are located near the site, but particularly in one part of the study area (presumably downwind). The incidence of housing units with excessively lead-burdened children is much higher in this area, compared to a baseline incidence of about 12 percent in other parts of the area mapped in Figure 1 of the study. The reference to the target cleanup area is gratuitous, since it is never shown or discussed relative to the sampling areas defined in the report.

4. We agree that average "soil lead levels decreased as the distance from the smelter increased", but radial distance alone does not describe the pattern of soil lead concentration as a reflection of physical processes of transport and dispersion. This should have been mapped.

5. We agree that "For small children, house dust served as the major vector of exposure. The source of lead in house dust was lead in paint and soil," but the analyses in the report omitted dust lead from the most important statistical models. This omission profoundly distorts and biases the results of the models.

6. It is probably true that "High concentrations of lead in paint in well-maintained houses did not contribute noticeably to lead exposure," but this proposition was not adequately proven in the report. The report confuses many of the analyses by using housing condition as if it were the primary predictor of blood lead and dust lead, whereas housing condition is in reality a modifying factor for the actual lead exposure variables.

7. We agree that "Lead intake was influenced by many personal variables," but this point is irrelevant for risk assessment, as these differences are part of normal inter-individual variability. As discussed in Section 3.6, the analyses in this report failed to use much of the potentially valuable questionnaire data about inter-individual differences.

8. It is probably true that "Education of the parents/guardians ... had a favorable impact on

children's blood lead," but the discussion in Section 1.3 shows that this proposition cannot be proven using data in the study. If true, this may largely explain the reduction in follow-up group. However, several other plausible explanations for the change cannot be precluded since there were no control groups in the study. This question is imbedded in a larger question. There has been a very high level of public awareness of lead hazards for some time because the controversy regarding this site has been going on for a long time. If education and parental counselling is effective in reducing childhood lead exposure, then one might assume that the general awareness of lead hazards through news media presentations and conversation with other people might have had a similar effect, reducing the blood lead concentrations for the community as a whole relative to the same environmental lead concentrations in communities with a lower level of awareness of lead hazards.

9. Relative source contributions cannot be established using the analyses in this report. This is a bottom-line question and requires that the analyses be completely redone. The reported results are highly compatible with the causal model we proposed in Section 3.4, that lead in soil is an important indirect source of lead in blood through the soil-to-dust pathway. Even though the variability in log blood lead is large, so is the effect of different household dust loadings large. These analyses, and in particular other analyses that use correct and appropriate model specifications as outlined in Section 3 of these Comments, are required to correctly estimate total direct and indirect contributions from soil lead and paint lead to blood lead.

6. EXTERNAL REVIEWS

These comments have raised a number of substantive technical issues that need to be addressed. We therefore suggest that reviewers of the next drafts of the Madison County Lead Exposure Study report include individuals with demonstrated technical expertise in these areas, so as provide the authors with appropriate review of their responses to the technical issues we have raised. While we hesitate to name a few individuals among the many qualified scientists, we believe that the following non-government scientists can provide high-quality scientific reviews or can recommend other qualified scientists as reviewers. They include:

Dr. William Gutknecht, Research Triangle Inst. -- methods for dust, soil, paint analysis

Dr. Steven Rust, Battelle Memorial Inst. -- statistical analysis of blood lead studies

Dr. Richard Royall, Johns Hopkins Univ. -- population sampling statistics

Dr. Roderick Little, Univ. Calif. Los Angeles -- design and analysis of sampling studies

Dr. David Jacobs, Nat'l. Center for Lead-Safe Housing -- environmental lead sampling

Dr. Michael Weitzman, Univ. Rochester -- pediatric lead poisoning, design of field studies

Dr. Ann Aschengrau, Boston Univ. -- epidemiology, sample design and analysis

Dr. Mark Farfel, Kennedy Institute, Johns Hopkins -- lead paint sampling

Mr. Ed Norman, Branch Head, Childhood Lead Poisoning Branch, North Carolina Department of Environment, Health, and Natural Resources, Raleigh, NC -- state lead studies

Dr. Joel Schwartz, USEPA, OPPE, on assign to WHO; after 9/1/94, Department of Biostatistics, Harvard School of Public Health -- lead expert on loan to WHO

PART 2. DETAILED COMMENTS

p. 2, para. 1. ABSTRACT: The statement about the lack of effects of soil lead and lead-based paint on blood lead cannot be made as general conclusions. House condition and parental education are confounded with location and house age, thus with distance from the smelter and with lead exposure. The effects of soil and paint lead can be substantially separated from behavioral factors, but not by the analyses in this report. See Part 1, sec. 3.

p. 10, lines 14-15. The use of concentric rings is not justified, since there is no a priori reason to believe that Pb dispersion around a smelter is symmetric. All of our studies around point sources find non-symmetric dispersion as measured by Pb in soil or in dust.

p. 10, last two lines. Not sufficient reason to exclude Pontoon Beach.

p. 11, lines 7-11. Splitting the sample by soil lead concentration isopleths would produce spatially contiguous "neighborhoods", which is a more defensible basis than using soil lead concentration without regard to location. These "neighborhoods" may or may not correspond to separating neighborhoods on the basis of socio-demographic factors that are known to influence blood lead, such as SES, ethnicity, or multi-family vs. single-family housing. Some reasonable spatial separation of these communities into smaller homogenous neighborhoods for statistical analyses should have been attempted.

p. 12, line 1. "The initial definition of sampling regions was somewhat arbitrary ..." Yes! See above. Did this make any difference in sample collection strategy? Show these on Figure 1.

p. 16, line 4. Was the paint condition coded numerically as shown here, 1 = intact, 2 = slightly peeling, ..., 4 = extremely deteriorated? Why not a non-linear coding with higher weight to greater deterioration? Can you provide photographs or drawings to illustrate these levels?

p. 16, lines 7-8. How was house condition coded numerically? See above. Were house condition and paint condition correlated?

p. 16, lines 9-10. The use of a community mean seems a very poor imputation strategy. What about predicting condition from house age, or from block or neighborhood mean? What about the use of dummy variables for missing values? See Rubin & Little's book on missing values. In any case, it is hard to understand why 15% of the values of this easily determined observation are missing, and why the missing values could not be filled in later at minimal cost.

p. 16, lines 15-16. "Obvious paint chips were removed prior to soil analysis." Was this information saved? The causal significance of this finding is that exterior lead-based paint contributes to lead in residential yard soil, which is evident in statistical analyses.

p. 16, last line, p. 17, first 2 lines. "Dust loading" should be used to define the total amount of dust collected per unit area, say as g/sq.m. "Dust lead loading" is the amount of lead per unit area, which is what the report used. The dust lead concentration is sometimes a better

predictor than the dust lead loading, since it often characterizes the presence of a strong dust lead source better than the dust lead loading. From a statistical point of view, dust lead concentration and dust loading constitute distinct "main effects" in a regression or analysis of covariance model, and dust lead loading is their interaction term. These may all be separately predictive of blood lead., albeit correlated.

p. 19, para. 1. Note that the interior paint score is the interior XRF reading times a four-level paint condition index, whereas the exterior paint score is the product of the exterior XRF reading times a three-level house condition index. Some explanation is needed.

p. 19, lines 7-8. Distance from smelter is not an adequate measure of spatial dispersion.

p. 20, lines 9-10. A better strategy would be to dichotomize data by neighborhoods, even if "neighborhoods" are defined by soil lead concentration isopleths. Even the reporting of statistics by community (Granite City vs. Venice vs. Madison) would be useful to the reader.

pp. 20-21. The hierarchical regression strategy developed in this report should be dropped, or should be justified in much greater detail. There are many possible data-driven approaches to variable selection in multiple regression, and different approaches can produce different sets of "optimal" coefficients as is demonstrated in most texts on multiple regression (Draper and Smith, or Daniel and Woods). This is a consequence of the correlation among predictor variables, since there is some fraction of the variance of the logarithm of blood lead that could be explained equally well by any of several predictors. A directed hierarchical regression strategy can only be justified on the basis of a postulated causal model. A plausible model is suggested by the report's exploratory analyses for blood lead (Table 10) and dust lead loading (Table 12, model 2), as sketched in Part 1, Section 3 of these comments. The structural equation modelling approach recommended in Section 3.5 is statistically unbiased and is a much more efficient method for estimating parameters in causal hypothesis testing.

p. 21, lines 4-7. Controlling for correlated covariates is one of the most important modelling issues in analysis of any observational study. The most common approaches, such as stratification or dimensionality reduction, are easily implemented using SAS. The "neighborhood" approach we suggested above should largely control for distance of smelter, age of house, socio-economic status (SES) and other variables, and is more appropriate to the scale of environmental assessments being carried out. Constructing composite variables by principal components analysis or otherwise may also be used to reduce dimensionality of the problem. However, the real problem is that soil lead and dust lead are separate media, but they are correlated. Both contribute to child blood lead by different pathways. The soil lead is a contributing fraction to dust lead. Blood lead is more highly correlated with dust lead than with soil lead. This suggests that soil lead is less important as a direct exposure medium than dust lead, but that soil lead is clearly a significant source for dust lead.

p. 22, lines 4-8. Why couldn't the analyses have been done with and without Pontoon Beach as a control group? See Section 1.

p. 23, para. 1. Does the non-participation group have different characteristics than the others

who participated? This question needs quantitative analysis, not anecdotal reports. What efforts were made to obtain more information about non-participants so as to compare them with participants? This may be a systematic source of bias.

p. 23, line 4. The non-participants' responses to USEPA actions should have been irrelevant. Did the interviewers fail to communicate the purposes of this study? In view of the long (five to six year) community awareness of the proposed EPA actions, the interviews should have been structured so as to clearly define the purposes and missions of the study sponsors. The proposed goals of the study are defined in the consent form (Page B-8). While the sponsors of the study are listed, this introduction does not seem to provide a characterization of the purpose of this study as distinguishable from the proposed cleanup actions. We are concerned that this may have contributed to the high non-participation rate.

p. 23, para. 2. There are certainly some suggestions that the non-response was correlated with biasing factors. For example, lines 10-11, one may presume that the families without telephones had lower SES or lower income, thus their children are more likely to have higher blood lead. The non-response sampling bias issues are known to every epidemiologist. Please discuss.

p. 24, para. 1. Reporting the numbers in the text makes it very difficult for most readers to determine the composition of the participating households. It would be useful to tabulate this in a two-way table, with the row factor giving the number of participating children less than 6 years in the household (0, 1, 2, or 3+) and the column factor giving the number of participating youths in the household (0, 1, or 2+). The number of families with pre-school children 230 (1 child) + 106 (2 children) + 14 (3 or more) = 350 familes/households, thus we have 388 - 350 = 38 households with no participating pre-school children. Please reconcile all numbers.

p. 24, lines 6-8. Location is important. Where were the multiple-sibling households located?

p. 24, lines 13-14. Location is important. Where were the ethnic (primarily African-American) families located?

pages 24-26, Participant Characteristics. Please provide tables for all of these cross-tabulations. Were any of the analyses stratified by subpopulation?

pages 25-26. Need to understand collocation of participant characteristics, many seem to be common measures of SES.

page 27, para. 1. The aggregate mean blood lead concentrations and percentages of children with elevated blood lead are almost meaningless without breaking out the location of the children. For example, if the Pontoon Beach children had been included in the study, would their presumably lower blood lead concentrations have been averaged in with all of the other children, thereby lowering the blood lead average even further? The important question that these statistics overlook is the spatial dimension of the elevated blood lead cluster, which is evident from the map in Figure 1 of the report. The map is almost impossible to read, but we counted (about) 39 houses or residential units in which children with elevated blood lead (at least 10 ug/dl) lived, out of a total of (about) 320 units, or 12 percent of the units. See Part 1,

Section 3.1 above. The averages should also have been adjusted for the differential non-participation rates in the different areas.

page 27, lines 12-15. Compare blood lead concentrations of ethnic groups after adjustment for neighborhood or SES or environmental lead.

page 28, para. 2. The repeat blood sample study needs to be adjusted for several reasons: (1) winter blood lead is almost always about 30 percent less than summer peaks; (2) "regression to the mean" because of sampling variability; this could have been evaluated if a similar sample of children with low blood lead had been taken; (3) the September study was itself a significant intervention activity that increased the parents' or caretaker's awareness of lead hazards. These are discussed in detail in Part 1, section 1.3.

p. 31, 4 lines from bottom. Many missing data on house age. How imputed? Were missing cases dropped from the analyses?

p. 32, lines 7-13. This is a completely inappropriate way of presenting the data. It would have been much more informative to have presented the percentage of children in each area with blood lead concentrations of 10 ug/dl or greater.

p. 32, lines 14-15. This is an extremely misleading statement. We agree that housing condition is a covariate that may affect lead exposure. However, without lead in some medium such as soil, dust, or paint, housing condition is at best a weak indicator of differential exposure to other lead sources because it is confounded with SES and other factor. If there is no lead in the house, there is no exposure to household lead. Housing condition should be treated statistically as an interaction term or confounder.

p. 33, para. 1. The report indicates the range of soil lead concentrations for composited samples. The range of soil concentrations from multiple samples within a yard is likely much larger. These 'hot spots' may indicate potential exposure sources beyond those suggested by the composite sample concentration.

p. 33, line 10. Is the difference of 89 ppm within specifications?

p. 33, line 15. Were the log-transformed data actually tested for normality? We are concerned that, because there may be different mixtures of lead sources in different parts of the Madison County sampling area, even the log-transformed data may not be log-normally distributed. What implications does the possible deviation from log-normality have for the statistical analyses?

pp. 36-39. Present results of binary splits in Tables. Present tables of correlation coefficients. Specifically identify missing value imputation or deletion strategies.

pp. 36-39. The binary splits that are most informative are those that divide children above and below 10 ug/dl. These must be tabulated.

p. 37, para.1. Use of the symbol 'r' for correlation must be explained for most readers.

p. 38, para. 2. Doesn't the strong and similar correlation of log(soil lead) with log(dust lead loading), log(1/distance), and house age (log transformed or not?) suggest a common factor?

p. 38, lines 5-6. The high correlation of soil with indoor lead paint may represent a secondary relationship because of a strong confounding with house age. Why comment on this, and then gloss over the much stronger and physically explicable correlations with distance and house dust lead loading?

p. 39, last para. The use of building condition as a primary predictor of blood lead is a very poor choice. This variable is highly confounded with many other variables, such as housing age and SES, that appear to be highly correlated with environmental lead in the Madison County study, but not in general. The report overlooks a basic axiom of exposure assessment: There is no exposure to a chemical if the chemical is not present. Even a badly deteriorated building does not pose a lead hazard if there is no lead in the paint or construction materials, no lead in surrounding soil, no lead in floor or furniture or carpet or window dust, no lead in the water supply. Building condition should be used as a modifier of exposure. The association of building condition, building age and SES may explain other correlations.

p. 40, para. Cigarettes per Day. Correlations with dust lead etc. probably represent confounding with SES and location.

p. 41, Regression Analysis para. Regression analysis is limited in its ability to deal with many correlated factors, as noted elsewhere. Environmental pathway analysis using structural equation system methods deals with this much more effectively, and also allows for adjusting the regression coefficients for the effects of "measurement error" in the predictor variables.

p. 41, Stepwise Regression para. How were the variables on the list selected?

p. 42, last 4 lines. If the stepwise regression method is not going to be used for the only thing that it can do well, why report the results? See Part 1, Section 3.7, and especially the predictor variable selection strategy discussion in the Dietrich et al. paper cited there. The stepwise regression model described in Table 10 is actually far superior to the hierarchical model proposed in the report, and in fact does capture the biological and environmental relationships much more effectively than the model in Table 12. It's still not right; see Part 1, Section 3.4.

p. 43, lines 12-13. "... house dust was not included as a potential confounder since the source of lead in dust was mostly paint and soil." This is a a major conceptual blunder, with serious consequences, and largely invalidates the analyses. See Part 1, Sections 3.4 and 3.5.

p. 43, para. 2. This is an extremely idiosyncratic collection of predictors for a hierarchical model. Exterior lead-based paint is strongly correlated with soil lead, probably representing a source term. Interior lead-based paint is strongly correlated with dust lead, probably causally, and is thus a predictor of blood lead, as is recent household refinishing. Water lead is a weak

predictor, confounded with house age and thus with building condition. We do not understand the justification for inclusion of confounding terms and omission of the most important direct predictor, household dust lead. See Part 1, Section 3.7, on modelling strategies.

p. 43, bottom line and p. 44, top 2 lines. The small R^2 values are attributable to the report's failure to appropriately include household dust as the primary exposure vector. Not surprisingly, since the analysis omitted the most important (but indirect) process in childhood soil lead exposure, it found a fairly small direct effect for soil lead. Much of the soil lead effect is buried in the confounded variables used in Model 1, especially the logarithm of CXI and the House condition. Since the regression model is not correctly specified, the conclusion about the direct effect of soil lead on blood lead may or may not be true; it is certainly irrelevant because soil lead is the most significant cause of dust lead, and dust lead is by far the stronger predictor of blood lead. See Part 1, Section 3.

p. 44, para. The Contribution of Soil Lead to Dust Lead. The authors' mis-specification of a total exposure model invalidates their analyses separating the paint contribution from the soil contribution to house dust. Since exterior lead-based paint is often a substantial source to lead in soil, the inclusion of an exterior lead-based paint term in the analysis proxies out a major part of the soil contribution to household dust. An appropriate multi-media pathway model would allow better separation of these effects. This study threw away an opportunity to obtain some direct information on the contribution of exterior lead-based paint on soil lead by sieving the paint chip particles out of the soil samples. Building condition is probably an important modifying factor in dust lead loading and in dust loading, but without lead from identifiable sources in soil and paint, there would be much less lead in dust whatever the condition of the house. Building conditon is a composite of interior and exterior paint condition, but one or the other of the component indices may be more predictive than the composite index; was this tested? Were the separate effects of paint condition and XRF reading tested? It seems unusual to include the product term ('interaction effect' in a statistical analysis) without including the separate terms ('main effects') as additional factors.

p. 44, para. on multiple children, and Table 13, page 79. Without adjustments or stratification for important confounders such as SES or neighborhood, this comparison is not very meaningful.

p. 45, para. 1. The purpose of the study, as stated here - "to determine whether children, under the age of six years, living in an environment with elevated lead levels in soil had elevated blood lead levels", is not the same as the objectives stated in the protocol submitted in 1991. The Protocol for the Multistate Lead Exposure Study, Illinois, Kansas, and Missouri, which should be part of this report, lists the following objectives:

"1. To determine the dose measures of lead and cadmium in blood and urine in target populations and compare them with dose measures found in comparable populations.

2. To determine the level of lead and cadmium of environmental media in target areas and compare these with levels of contamination observed in comparable non-target areas.

3. To characterize the distribution of selected biomedical test values in target area populations and compare them with the distribution of biomedical test values observed in comparable area populations.

4. To compare the distribution of selected biomedical test values in target and

comparable populations and compare them with standard reference ranges for these tests.

5. To determine the extent to which environmental, behavioral, occupational, and socio-economic factors influence exposure to lead and cadmium in target and non-target populations.

6. To determine the extent to which internal dose measurements of lead and cadmium in blood and urine are associated with the distribution of biomedical test values.

7. To determine the extent to which exposure has occurred in populations living in areas with both mining and industrial emissions compared to populations living in areas with industrial emissions only."

It is questionable whether conclusions on questions which the study was not designed to answer are valid. However, given the stated purpose of the report, it should have at least answered the question, whether the study observed a difference in the percentage of yards with soil lead levels greater than/less than 500 ppm for children whose blood lead levels are greater than 10 ug/dl as compared to yards with soil lead levels greater than/less than 500 ppm in children whose blood lead levels are less than 500 ppm.

p. 45, para. 2. The demographic differences between most-exposed and least-exposed children should be emphasized.

p. 45, second sentence from bottom. Cite references for reduced lead in gasoline.

p. 45, 2 lines from bottom. "lead exposure factors do not occur in isolation." A key point, not adequately handled in the analyses.

p. 46, last sentence. The comment about mean blood lead of 5 ug/dl is irrelevant to health risk assessment. The finding of 6.9 ug/dl in the Madison County study is more relevant, but still misses the point. The real point of the study is that 26 percent of the houses in our Area A defined in Part 1, Section 3.2, have children whose blood lead concentrations exceed 10 ug/dl, which is a **health-based blood lead level of concern.** Furthermore, these children are found in an area in which soil lead concentrations and other lead exposure indices are relatively high.

p. 47, lines 1-11. Irrelevant. The current blood lead level of concern for EPA and CDC is 10 ug/dl, and that should be used as the reference value for all health risk assessments in the report. The older blood lead levels of 25 ug/dl are now known to be unsafe and do not merit any further discussion. In the 1960's, 40 ug/dl was considered safe, whereas the current CDC guidelines mandate medical treatment at 45 ug/dl and above. Stay with 10 ug/dl as a health effects level.

p. 47, last two sentences in para. 1. The errors in analyses described above invalidate these "findings". Behavioral factors are important **modifiers** of exposure. But, if there were no lead in the environment, there would be no exposure, and that is not the case in Granite City since many children had elevated blood lead: 16 percent in the whole area; 19 percent among African-American children; and probably a much higher percentage closer to the smelter, since 26 percent of the housing units had children with elevated blood lead concentrations.

p. 47, second para. Education of parents is a significant component in awareness and avoidance of lead hazards, and may be a better modifier of exposure than income or other partial indicators of SES (socio-economic status, possibly as measured by the Hollingshead index).

p. 48, line 11. "House dust was ... not included in the hierarchical regression against blood lead." This therefore invalidates any other findings from that model.

p. 48, lines 14-16. "Simultaneous regression ... would have produced unpredictable [unstable] and invalid partial regression coefficients." The mis-specified form of the model used in the analyses may have created the problem. A pathway model with additive effects from paint, soil, and dust, and multiplicative modifiers from house or paint condition and behavioral variables, would probably have reduced the problem of multi-collinearity and provided a better basis for judging whether the lead sources near the smelter are similar in effect to those farther away. See Part 1, Section 3.

p. 48, last para. The variables that were discarded in the analyses (age of child, hours spent outdoors, and child behavior) are precisely those that are most useful in reducing the inter-individual component of variability in blood lead. See Part 1, Section 3.6.

p. 49, line 5. "37 % of the exposure ..." The authors should have said "37 % of the variance in the logarithm of blood lead"

p. 49, lines 6-8. By ignoring the soil-dust-blood pathway, the report greatly underestimates the role of soil as an indirect source of lead in blood. We have described above how the inclusion of house condition as a confounding variable is very inappropriate. The conclusion that the maximum contribution of soil is 3 percent is unwarranted; this is a minimum contribution, and a substantial underestimate. By the same fallacious arguments presented in the report, the maximum contribution of lead-based paint is also 3 percent at most. Actually, neither conclusion is correct since the analyses on which the conclusions are based are so badly flawed. This paragraph needs to be completely revised.

p. 50, lines 3-12. This section needs to be rewritten. A candid description of the failures of the authors' modelling strategy would explain the instability of the regression coefficients. See Part 1, Section 3.7.

p. 50, last 2 lines, and p. 51, lines 1-8. As explained in Part 1, Section 1.3, the follow-up data cannot be used to test the hypothesis that intervention was responsible for the decrease in blood lead concentration. Other explanations, such as regression to the mean and the impact of initial recruitment in the study cannot be precluded as explanations. This study was not designed to test the effectiveness of intervention, and lacks the control groups that would allow valid inference about intervention.

p. 51, lines 4-8. If the summer blood lead peak in Madison County had passed, then peak blood lead concentrations should be even higher than observed in this study. We would expect about a 30 percent decrease to winter low values, even if a hypothetical winter peak exists.

p. 51, para. 2. Many behavioral factors affect the seasonal variations in blood lead, which we still see in the control groups in the USLADP cities. Seasonal variation of blood lead in these recent longitudinal studies are still at about 30 percent of the annual average concentration. Blood lead concentrations in most longitudinal studies increase up to ages 18 to 36 months, then

decrease (the regression models used in this report did not adjust for a non-linear relationship with age). Large reductions in blood lead associated with environmental abatement have occurred in some recent studies, such as Kellogg ID, and greatly exceed any possible blood lead measurement error. The 15 percent decrease in blood lead associated with soil and dust abatement in the Boston USLADP study greatly exceeds the measurement uncertainty associated with the mean of a sample of 150 children. The seasonal variations and abatement effects are real and should be discussed in the report.

p. 51, para. 1. The discussion on seasonal fluctuations is incomplete. The discussion on the changes in blood lead from abatement or removal (of child or of source) is extremely distorted and does not reflect the large reductions in child blood lead in other smelter communities, such as East Helena MT and in Kellogg ID, following either remediation or parental awareness intervention or both.

p. 52, para. 1. The magnitude of the fluctuations in repeat sampling and the magnitude of the analytical errors, including drift, should be included in the discussion if this is relevant to the Study report. The relevance of this paragraph is unclear. If not needed, drop it.

pp. 53-54. Conclusions do not follow from the analyses. These are discussed in Part 1, Section 5.

p. 70, Table 10. log blood lead level? Also, use 'log of dust lead load'.

p. 71-73 "Soil composition" is clearly a misnomer. The correct entry is 'logarithm of soil lead concentration in composite sample'.

p. 74. Mislabelled as p. 80. See Part 1, Section 4.

pp. 75-76. These are terribly misleading plots. Use ordinary histograms of blood lead by age.

Appendix K—Response to Comments of US EPA Reviewers Regarding the Granite City Lead Study Draft Report

RESPONSE TO COMMENTS OF U.S. EPA REVIEWERS REGARDING THE GRANITE CITY LEAD STUDY DRAFT REPORT

The subject review document is presented in two parts. The first part is a lengthy and detailed discussion, termed a "general issues" section. The second part of the review document contains specific comments. However, the 'general' comments section actually recapitulates all of the specific comments contained in the second half of the document. In order to facilitate understanding the relationship of the comments and responses, the responses presented below are numbered so as to correspond to the numbered comments in the general issues section.

1.1 Participation by zone has already been presented.

We made an extra effort to recruit in the high soil lead area at the lower SES, close proximity households. Phone calls to residents started with this area and continued throughout the study. Additionally, households with no phone were visited personally and repeatedly in order to recruit. Transportation needs were met and every effort made to accommodate potential participants.

1.2 The term "control group" implies that there is a clear definition of what, how, and why we are controlling by design or analysis strategy. In this case Pontoon Beach was different with respect to SES and living conditions (e.g. newer homes; a trailer park). They were not comparable to residents in our main study area (composed of old houses situated in or near the proposed cleanup area). Inclusion of these individuals would have introduced a bias as a result of these clear differences. Residents from neighboring areas of Granite City were far more comparable to our target group, and therefore, provided the best frame of reference for evaluating the effects of soil lead.

Use of a "control group" is actually an error in the design of studies of the effects of residential lead, unless it can be shown that the control group is like the study group in *every* respect except soil lead level. Our sample of subjects drawn from a more homogenous population spread over a distinct gradient of soil lead levels is the only sensible study design under these conditions.

1.3 This is a curious argument which seems to suggest that reported blood-lead elevations were not real (rather, a statistical anomaly) and, therefore, the observed declines were not real. Re-sampling of blood lead, combined with counselling intervention, resulted in a greater drop in blood lead than

expected. A recent re-analyses of this data by Battelle (on behalf of the USEPA for a report "Review of Studies Addressing Lead Abatement Effectiveness") found that the "mean blood-lead concentrations.....decreased significantly at the four-month follow-up measurement, but rose somewhat by the 12-month measure. Despite this rise in blood-lead concentration, the averages at 12 months remained significantly below initial levels" (Niemuth, personal communication).

In the past seasonal fluctuations in children's blood lead levels have been reported with principal emphasis on the summer peak. However, Marrero et al. (Conn. Med. 1983; 47: 1-5) reported two peaks one in late winter and one in mid-summer. They also found that the low levels were at most about one third less than the peak value. Our initial blood lead determinations were made in late August and early September when the "mid-summer peak" (it is questionable whether there still is such a thing) had already passed. In January the blood lead levels had decreased to half their original value where they remained for a year. The seasonal fluctuations observed many years ago were closely associated with the sale of gasoline, fluctuations in air lead levels, weather patterns and traffic density (Caprio et al. Arch. Environ. Hlth. 1974; 28: 195 - 197). Since lead has been phased out of gasoline seasonal fluctuations have been less of an issue.

It is known that children's blood lead levels also decrease as children get older. The magnitude of this decrease is much less than we experienced in our follow-up study. This fact is very convincingly demonstrated by the EPA study in Boston where the decrease even with some remediation only ranged from 0.52 - 2.44 μg/dL after a one year follow-up.

Finally, it has been argued that repeat blood lead levels would always be slightly lower since data would have a tendency to regress to the mean. This may be a valid statistical argument but in practice from a clinical point of view the goal of lowering blood lead levels was achieved. It would be unethical not to give part of the group of children with elevated blood lead levels the benefit of counselling. Using children with blood lead levels below 10μg/dL as controls would be an option although in such a group based on our experience any decrease would be much smaller. It is therefore unclear whether that would represent a true control group. However, the main reason for not having such a control group was the lack of money. We had to use the same laboratory and CDC was kind enough to analyze the additional elevated blood lead levels free of charge and the hospital laboratory including the phlebotomists also helped us out in this regard since the group of children that was re-bled was not overwhelming. Money for follow-up and treatment is not available for these kinds of "Superfund" studies. Finally, if there is a central tendency it must be small based on the EPA data from the Tri-City studies.

2.1 It was the USEPA (represented by a number of individuals including one of the reviewers) that developed and approved the protocol for sampling house dust. The USEPA developed criteria for evaluating the qualifications of prospective contractors, and selected the contractor who did the work. The USEPA has all of the environmental data in its possession.

2.2 Again, the USEPA developed the protocol for sample collection and Quality Assurance/Quality Control (QA/QC). The USEPA selected and supervised the contractor that collected the samples. The USEPA has the data.

2.3 Again, the USEPA developed the protocol for all environmental sample collection and QA/QC. The USEPA selected and supervised the contractor that collected the samples. The USEPA has the data. We find it curious that USEPA chooses to question methods that met with their approval prior to collecting the samples.

Ten soil samples were collected from the primary play areas in the yard around each house. No soil samples were taken from within the drip line of the house. A composite soil sample was made from the ten samples. This procedure should have yielded a representative soil sample from the yards and play areas. Since the great majority of the yards were very small, it is highly unlikely that the soil sampling protocol could have yielded unrepresentative soil lead results.

2.4 In both the inside (CI=1,2,3,4) and the outside (CO=1,2,3) rating of the condition of the house, the higher score was for the worst condition. This is a routine rating similar to that used by certified contractors specializing in lead paint inspection programs.

3.1 Although it is potentially useful to know that blood lead peaked in our study sample at around two years of age, the simple descriptive statistics that we present convey this information most directly. The simple graphic we present shows exactly at what age, and at what level, blood lead levels peak. It also shows the slope of the decline with age. Compared with this graphic presentation, the quadratic regression term recommended by the reviewer would have no meaning to most readers of the report.

Employing an nonlinear age covariate in blood lead regression models could increase slightly the amount of blood lead variance accounted for by age. That would have the effect of reducing slightly the amount of variance in blood lead remaining for other variables, such as soil and dust, to explain. However, including a quadratic expression for age would not

appreciably change the overall blood lead R^2, nor would such a term improve our understanding of the influence of age or soil on blood lead.

3.2 The fact that our subjects lived in irregularly shaped residential areas, at varying distances form the closed smelter, is a strength, not a problem, in this study. None of our analyses, besides those involving distance from the smelter, depend in any way upon spatial location.

Soil lead is not uniformly distributed around the closed smelter either. Although soil lead levels decrease with distance from the closed smelter, there are hot spots and irregularities in the soil lead distribution throughout the study area. The sampling areas (zones 1--4) were used only to obtain a representative sample of homes and children across the entire *range* of soil lead levels, regardless of location. Neither distance, nor any other location variable, enters into the main multiple regression/correlation analysis - the point of which is to use the *joint distribution* of blood, soil, paint, dust, and water lead measures in the homes and yards of study participants, regardless of location, to understand how the variables are associated with one another.

The spatial distribution of blood lead is of interest because it can sometimes help to locate and explain clusters of high blood lead cases. That is why we depicted the physical location of the subjects in the study area. However, it was shown that distance is associated not only with soil lead and blood lead, but with SES, building condition, behavior, and other factors that influence blood lead. Simultaneous spatial depiction of all of these factors cannot be interpreted. That is the role of multiple regression/correlation analysis. The problem with the unadjusted bivariate tabulation presented by the reviewer in TABLE 1 of the EPA comments is that it totally ignores confounding by these other factors, which we have shown to be present.

We agree that the reader should not have to work hard to extract pertinent information, but would point out that the map used was included to provide a general sense of spatial distribution of the participants rather than an absolute determination of the relationship between the smelter and the blood levels (if for no other reason than to protect confidentiality). To gerrymander the map in the matter described goes beyond the questions asked in this study and gives the impression of attempting to force the data to confirm to previously held expectations.

3.3 This section presents a false and ridiculous argument. The reviewer took a meaningful linear multiple regression equation, mistakenly attempted to exponentiate the entire equation, and

transformed it into a meaningless expression. The reviewer obviously misunderstood both the use of logs of the environmental and blood lead variables, and the meaning of the original regression equation.

First, it should be understood that the use of log-linear transformations made only a small difference in any of the analyses. However, since the environmental and blood lead measures were not normally distributed (they were skewed, with a few extreme high values), log transformation of the raw values resulted in more nearly normal distributions, and some improvement in the blood lead variance accounted for by the environmental measures. The methods used to analyze these continuous variables assume normal distributions of the variables, although the methods are robust enough to permit fairly radical departures from this assumption.

3.4 The statements in this section are also false, and indicate a lack of understanding of hierarchical regression. The reviewer incorrectly states that R^2 is not a "measure of effect", when the opposite is true.

> "..., one of the most attractive features of MRC is its automatic provision of proportion of variance and correlation measures of various kinds. These are measures of 'effect size,' of the magnitude of the phenomena being studied."
>
> Cohen and Cohen, in *Applied Multiple Regression/Correlation Analysis for the Behavioral Sciences*, John Wiley & Sons, New York, 1975. p. 5-7.).

In our regression analysis of soil lead and blood lead we avoided including variables that could possibly confound the soil/blood lead relationship if including the other variables could over-adjust (reduce) the size of the soil lead effect. The argument presented by the reviewer makes the incorrect assumption that including other variables might have increased the soil lead contribution. That is impossible. Every "adjustment" variable included in the regression model ahead of soil lead would necessarily account for some additional portion of the blood lead variance, thereby further reducing the variance left for soil to account for.

The reviewers do not appear to understand the parameter estimates in our report (e.g in Table 10). Parameter estimates found at the final step in any stepwise multiple regression procedure capitalize on chance and are not reliable. They should not be interpreted out of context. Stepwise procedures are only an aid in early exploration of the data, to be used along with

careful consideration of the simple correlation matrix, and to be interpreted in the context of the earlier steps of the procedure, in which other variables enter and leave the equation.

The individual parameter estimates in any single step of a multiple regression model do not adequately express the adjusted contributions of the main study factors. In multiple regression, there is no substitute for set-wise hierarchical regression when attempting to adjust for possible confounding.

3.5 Pathway analysis as proposed is a subjective exercise that depends upon the assumptions of the analyst. We presented all of the descriptive statistics, bivariate statistics, and multivariate statistics used in our interpretation of the data. In particular, we described the importance of paint as a major contributor to dust lead in our study.

The point of Table 12 is missed entirely by the reviewer of this section, who misinterpreted the parameter estimates for paint, dust, and soil presented in the second model. The correct interpretation of this analysis rests on the increment in R^2 when soil is added to Model 1.

In Model 1, water makes no difference, but it was one of our main environmental measures, and it cannot be viewed as possibly over-adjusting the paint and soil effects, so we included it. Paint and building condition are obviously linked, as paint lead is much more likely to find its way into house dust, and to be available for ingestion, if the building is in poor condition. Paint and building condition account for 26% of dust lead variance. The addition of soil lead measures account for another 6% of dust lead variance, less than 1/4 the value of paint. Interpreting only the parameter estimates for the variables in Model 2 ignores the central meaning of the hierarchical analysis.

3.6 As stated above, adding behavioral or other variables to a hierarchical regression model can only reduce the variance accounted for by soil. The reviewer seems to want to find some set of variables that lead to a higher simultaneous parameter estimate for soil, regardless of how little variance is explained by the individual variables, or how all of the other environmental variables are effected by the factors the reviewer wants included in a single analysis. Such an analysis is meaningless. Behavioral variables can over-adjust the effects of the main environmental variables, including soil, because behaviors are the pathways for environmental lead to reach the blood. It is incorrect to think that a better understanding of these variables can result from such an approach.

We have presented and discussed numerous bivariate relationships involving environmental, behavioral, and other factors, in order to show the considerable intercorrelation of

these variables. Part of the point of that discussion was that we did not feel that it was possible to interpret multivariate analyses if we included all of these variables at once.

3.7 The comments in this section are correct, but this is exactly the opposite of the point made by the reviewer in the preceding comment 3.6!

Our analysis avoided problems of multicolinearity by not including variables that could be proxies for one another. None of the variables included in the hierarchical regression models we presented are linked in this way.

3.8 While it is true that measurement error tends to reduce the magnitude of associations, this is equally true for all of the variables in this and any other study. This does not change the relationship of the variables as long as the errors in measurement are not systematic.

We do not believe that there were systematic errors of measurement in this study. As stated above, we used a small set of key predictor variables, and did not have any problem with multicolinearity, or over-adjustment of the soil lead effect.

4.1 We used 500 ug/g soil lead, and 10 ug/dl blood lead to conduct some two-group analyses, in addition to conducting other categorical and continuous data analyses. There were two reasons for conducting categorical analyses on these continuous data: 1. The ATSDR requested that we present part of our analysis in this way; 2. These cut points relate to *a priori* cleanup and blood lead levels set by EPA and CDC, respectively.

4.2 We agree that figures and graphs are helpful. Many more figures and graphs could be presented. However, the document is already quite long, and there is a limit to the amount of information that can be presented in this form. We presented figures and graphs when ever we thought that doing so would clarify a point of discussion.

4.3 The enlarged maps created by the reviewers indicates that our map was not as useless as stated. However, as previously stated, providing highly detailed maps would violate confidentiality of participants and exceeds the scope of the questions addressed by this study.

4.4 Confidence intervals can be estimated from the data provided, if it is thought by the reader to be important. We find little reason to believe that this is the case, since both the overall, and specific estimates of blood lead variance accounted for by the study factors is quite small in any event, and that is what really matters.

5.1 The facts speak for themselves. Our language choices differ. The majority of our higher blood lead values were not highly elevated (10.1-15μg/dl). These slightly elevated levels were largely in children from relatively poor, unemployed families, living in run-down houses. The numbers also are similar to those measured in other urban areas in Illinois or estimated statewide in general. Our interpretation is consistent with recommendations made by CDC in their most recent statements (Oct.'91). We are glad to note USEPA's use of the CDC's guidelines and would request that they review CDC's recommended intervention for children with blood lead levels below 20ug/dl. The intervention recommended is to provide counselling regarding lead sources, cleaning, and nutrition, which was done as a matter of course with some success. No environmental intervention is called for by CDC or those utilizing their guidelines at these low blood lead levels.

5.2 The reviewer does not understand that age was intentionally not used in the regression analysis (age was not "entered as a monotone predictor", as the reviewer states). This is because age is a proxy for exposure - through mouthing behavior that enables the ingestion of dust, paint, and soil. Adjusting the contribution of the environmental lead sources for dependence on age would clearly result in over-adjustment, thus reducing the blood lead variance accounted for by the environmental measures. Note that only children under six were used in the analyses. While there is a wide range in the behavior of children in this age group, the play and mouthing behaviors that produce lead exposure are present over the entire range. That is why the 6 months through 6 years age group was the focus of this analysis.

5.3 The correlation of distance and blood lead was reported. There were other important correlations with distance that were also reported (e.g. parent's education, income, age and condition of the houses). Note that actual soil lead measures are used in the main regression analysis, not a proxy such as distance or location. A much better indication of the association of blood lead and soil lead is obtained by direct analysis of these two factors than can be gained by gerrymandering neighborhood subunits of the sample and speculation about clusters.

The comments here, as elsewhere in the review document, mistakenly focus on univariate and bivariate interpretation of soil lead associations, when the report makes clear that the soil lead data are confounded.

As noted above, the sampling zones were not used in the analysis. They were used only to draw a sample of households that spanned the full range of soil lead levels in an otherwise fairly homogeneous community. We directed extra effort at recruiting households from the central sampling zone in order to

be sure we had adequate representation of the most highly (soil) exposed part of the population.

5.4 The USEPA has such maps already, and can use the soil data they collected for this study to do additional mapping of the distribution of soil lead in the study area if that is their interest.

USEPA soil lead maps were used as a basis for study subject selection. Those maps helped us to obtain a representative range of residential soil lead levels. However, as noted above, we used the joint distribution of soil lead levels measured in the subject's yards, along with other study variables, in our analysis of the predictors of blood lead. Actual soil lead level, not "radial distance", is the basis for our analysis and interpretation of the association of soil lead and blood lead.

5.5 This review comment is clearly false. We were very specific in our analysis of the contribution of dust lead to blood lead in our report, as well as in our analysis of the contribution of paint and soil to dust lead. It would have been a mistake to include dust lead in the analysis of soil and paint lead (as recommended by the reviewer). Since dust lead is almost entirely dependent on the lead in paint and soil, multicolinearity in the regression of all three environmental variables against blood lead could only produce a meaningless regression model.

5.6 The fact that ratings of overall building condition, as well as ratings of the immediate condition of paint at the point of XRF measurement increased the predictive value of paint measures supports our statement about the importance of this factor.

5.7 Inter-individual differences in behavior were important on an individual level. Such factors as hobbies and work related exposures were generally experienced by only a single family, and had no statistical value in the analysis. Important behavior-mediated exposures of this type must be considered on an individual basis, unlike paint and soil levels, which can be evaluated on a statistical level.

5.8 The speculation by the reviewer may, or may not be correct. The argument presented by the reviewer supports our decision not to include education, income, or other similar SES and behavioral factors in the main hierarchical regression model. It is not clear whether including these factors would correct for confound or over-adjust the effects of the environmental measures.

5.9 This statement by the reviewer that our analysis cannot establish the contribution to blood lead of the environmental measures in our study is nonsense. That is exactly what our hierarchical analysis demonstrates.

6.0 We appreciate the list of names of individuals the USEPA feels are qualified in this area. Dr. Kimbrough has had numerous discussions with Dr. Weitzman, one of the experts mentioned, and was involved in the initial stages of the design of the Urban Soil Lead Demonstration Project in Boston. Dr. Aschengrau was also involved in that study.

The detailed comments provided by the USEPA reviewers reiterates the points raised in their general comments. The same points are addressed in our responses to those comments and will not be repeated here.